

2014 Medicare Prior Authorization Criteria

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POLICY NAME: ABILIFY MAINTENA

Affected Medications: ABILIFY MAINTENA (aripiprazole suspension, reconstituted)

Effective Date: <u>08/01/2013</u> Last Review Date: <u>5/22/2013</u> Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required	☐ Diagnosis of schizophrenia and on maintenance treatment AND	
Medical	☐ The patient has a history of non-compliance and/or refuses to utilize	
Information:	oral medication. AND	
	☐ The patient has received at least ONE of the following:	YES / NO
	□ oral aripiprazole (Abilify),	
	☐ Abilify Maintena or	
	☐ Abilify solution.	
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion		N/A
Criteria:		IV/A
Age		N/A
Restriction:		14/74
Prescriber	☐ Psychiatrist or receiving input from a psychiatry practice	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: ACTEMRA

Affected Medications: ACTEMRA (tocilizumab)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved	indications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	notes within the m Documentation of For treatment of R Laboratory te Anti-Cyclic Rheumatoid Facto Negative L interferon prior to re For positiv receiving t	nost recent 6 months. Fromplete & current to RA: est must confirm diagroup (RF) and the release assay equest. OR ve latent TB, patient materials and the reatment for LTBI. It JIA, pediatric patient receiver) AND inadequate received.	reatment course required. rosis of Rheumatoid Arthritis: Antibody(anti-CCP) OR ith either by TB skin test or an (e.g., QFT-GIT, T-SPOT.TB) nust have completed or as must have active systemic esponse, contraindication or	YES / NO
Appropriate Treatment Regimen & Other Criteria:	2 DMARDs (h minocycline, s Patient has fa agent: abatac tocilizumab(A infliximab(Re Subsequent appro Treatment su following inst	niled at least 12 weeks hydroxychloroquine, le sulfasalazine) AND hiled at least 12 weeks tept (Orencia), rituxim hotemra), adalimumab micade), certolizumab bval requires document foccess/failure must be	(Humira), entanercept(Enbrel), o(Cimzia), golimumab(Simponi ntation of treatment success. documented with one of the CDAI, RADAI, PAS, PASII, RAPID,	YES / NO
Exclusion Criteria:	tocilizumab(Acteminfliximab(Remicae	de), certolizumab(Cim	mira), entanercept(Enbrel), zia), golimumab(Simponi) requested medication	YES / NO



Age	☐ For indication of systemic-onset JIA, may approve for children and	YES / NO
Restriction:	adolescents 18 years of age or younger.	125 / 110
	☐ For RA, ≥ 18 years old	
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	r's chart notes.



POLICY NAME: ACTIMMUNE

Affected Medications: ACTIMMUNE (Interferon Gamma 1 b)

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved indi	ications not otherwis	e excluded from Part D.	CONFIRMATION*
				YES / NO
Required	☐ FDA approved indicat	ion must be docume	nted in the member's chart	
Medical	notes within the most	t recent 12 months		
Information:	│ │ □ Patient's BSA must be	documented along	with the prescribed dose.	YES / NO
	Tatione's 23, timase se	a documented drong	with the presented dose.	
Appropriate				
Treatment				NI/A
Regimen &				N/A
Other Criteria:				
Exclusion	☐ Coverage under Part I	D will be denied if co	verage is available under Part	
Criteria:	A or Part B as the med	dication is prescribed	and dispensed or	YES / NO
	administered for the i	•	·	•
Age				N/A
Restriction:				IN/A
Prescriber				NI/A
Restrictions:				N/A
Coverage	☐ Approval = 12 months	s, unless otherwise s	pecified.	YES / NO
Duration:				
*Approvals require	that all holded regions in t	he 'confirmation' col	umn he documented in memb	er's chart notes



ADCIRCA

Affected Medications: ADCIRCA (tadalafil)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved in	ndications not otherw	rise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:		•	ght heart catheterization OR	YES / NO
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion Criteria:	☐ Patient requires nit	rate therapy on a reg	ular or intermittent basis.	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:		ths, unless otherwise	•	YES / NO
*Approvals require	that all bolded regions in	n the 'confirmation' c	olumn be documented in memb	ber's chart notes.



POLICY NAME: ADEMPAS

Affected Medications: ADEMPAS (riociguat)

Effective Date: <u>03/01/2014</u> Last Review Date: <u>09/23/2013</u>

Part D: Yes Part B: No

Member:	DOB: ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved indications no	ot otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	PAH	nbolic pulmonary hypertension (CTEPH) onary arterial hypertension (PAH) WHO	YES / NO
Appropriate Treatment Regimen & Other Criteria:	diuretics oxygen, digoxin Failure of the following therapy clas PDE5 inhibitors AND Endothelin receptor antagonists	nould be considered: anticoagulants, esses: S OR prostanoids locumentation of treatment success:	N/A
Exclusion Criteria:	 □ Pregnancy □ Creatinine clearance ≤15 ml/mi □ Severe hepatic impairment □ Concomitant use with nitrates (□ Concomitant use with PDE inhib vardenafil) 		YES / NO
Age Restriction:	☐ Age > 18 years		YES / NO
Prescriber	☐ Prescribed by or in consultation	with a cardiologist or a pulmonologist	YES / NO



Restrictions:		
Coverage Duration:	 □ Initial approval = 6 months □ Subsequent approval = 12 months, unless otherwise specified 	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in members	er's chart notes.



POLICY NAME: AFINTOR DISPENZ

Affected Medications: Afinitor Disperz (Everolimus tablets for oral suspension)

Effective Date: 03/01/2014
Last Review Date: 09/23/2013
Part D: Yes Part B: Yes

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved	indications not other	wise excluded from Part D.	CONFIRMATION*
				YES / NO
Required	☐ Subependymal G	iant Cell Astrocytoma	(SEGA) diagnosis.	
Medical				YES / NO
Information:				
Appropriate	☐ Patient has SEGA	associated with a tub	erous sclerosis complex (TSC)	
Treatment	that requires ther	apeutic intervention h	out is not a candidate for	
Regimen &	curative surgical r	esection		N/A
Other Criteria:				
Exclusion	□ Advanced horm	one receptor-positiv	e, human epidermal growth	
Criteria:	receptor 2-nega	tive breast cancer, a	dvanced neuroendocrine	
	tumors of pancr	eatic origin, advance	ed renal cell carcinoma, renal	YES / NO
	angiomyolipoma	a with tuberous scle	rosis complex, renal	
	transplantation.			
Age	□ ≥1 years			
Restriction:				N/A
Prescriber	☐ Must be prescribe	ed by or in consultatio	n with an oncologist	N/A
Restrictions:				IV/A
Coverage	☐ Approval = 12 mo	onths, unless otherwise	e specified.	YES / NO
Duration:				
*Approvals require	that all holded regions	in the 'confirmation'	column he documented in memb	er's chart notes.



ALPHA1-PROTEINASE INHIBITOR

Affected Medications: ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:		ndications not otherw	rise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	□ approve in par antitrypsin sei 80 mg/Dl AND		retreatment) alpha1- 11 microM (11 micromol/L) or	YES / NO
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion Criteria:	☐ COPD without a ☐ alpha1-antitryp deficiency-indu ☐ bronchiectasis	ment of cystic fibrosis alpha1-antitrypsin defi sin deficiency without ced hepatic disease is (without alpha1-antit A deficiency (≤ 15mg/	ciency, lung disease (even if present), OR	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Approval = 12 mon	ths, unless otherwise	specified.	YES / NO
*Approvals require	that all bolded regions i	n the 'confirmation' c	olumn be documented in memb	er's chart notes.



AMPYRA

Affected Medications: AMPYRA (dalfampridine)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Part D: Yes Part B: No

Covered Uses:		All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		Plus patient already started on dalfampridine extended-release for	YES / NO
		Multiple Sclerosis (MS).	
Required		Documentation of dosing and patient renal function	
Medical		(height / weight and serum creatinine OR eGFR OR CrCl)	VEC / NO
Information:		If dosage > 20mg per day, then documentation supporting using greater than maximum recommeded FDA dose.	YES / NO
Appropriate		For initial approval for MS, authorize for 90 days.	
Treatment Regimen & Other Criteria:		After up to 90 days of dalfampridine extended-release therapy, if MS patient has had a response to therapy as determined by prescribing	YES / NO
other criteria.		physician (eg, increased walking distance, improved leg/limb strength, improvement in activities of daily living), then an additional authorization is allowed.	,
Exclusion		History of seizures,	
Criteria:		Dose > 10 mg twice daily OR	YES / NO
		Creatinine clearance ≤ 50 mL/min.	
Age Restriction:			N/A
Prescriber Restrictions:		If prescribed by, or in consultation with, an MS specialist.	YES / NO
Coverage		Initial Approval = 90 days.	YES / NO
Duration:		Subsequent Approval = 12 months, if patient had a response.	
*Approvals require	that	all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



POLICY NAME: ANAGRELIDE

Affected Medications: AGRYLIN, ANAGRELIDE

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required	☐ Patient has a diagnosis of thrombocythemia secondary to a	YES / NO
Medical	myeloproliferative disorder.	TES / NO
Information:		
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion	☐ Severe hepatic impairment.	YES / NO
Criteria:		11.5 / 110
Age		N/A
Restriction:		IN/A
Prescriber	□ Oncologist or hematologist	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in mem	ber's chart notes.



ANTIHEMOPHILIC FACTOR (FACTOR VIII) CONCENTRATES

Affected Medications: Advate®, Helixate® FS, Kogenate® FS, Recombinate™, Xyntha™, Hemofil®M,

Monoclate-P®

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION*
	□ Acquired Hemophilia A.	YES / NO
Required	Hemophilia A – Primary Prophylaxis	
Medical	☐ Factor VIII levels <1% of normal (age 2+)	
Information:	Hemophilia A – Secondary Prophylaxis	
	☐ History of intracranial hemorrhage Factor	
	☐ Levels <1% and one or more joint bleeds	
	☐ Children under age 2 with Severe Hemophilia A (Factor VIII < 1%	
	normal) who have had one or more joint bleeds, and for whom the	
	benefits of prophylaxis outweigh the risk of central venous line use (if applicable)	YES / NO
	Hemophilia A – High Risk Prophylaxis	
	☐ For minor and major non-elective surgical	
	procedures	
	Immune Tolerance Induction (ITI)	
	☐ Inhibitor titer <10 Bethesda Units before start of ITI therapy	
Appropriate	Primary and Secondary Prophylaxis:	
Treatment	☐ All trough level monitoring must be recorded in chart notes	
Regimen &		
Other Criteria:	ITI	YES / NO
	may continue until inhibitor levels approach zero (<0.6 BU/mL) and	,
	factor levels show normal recovery (>66%) and/or FVIII half-life is	
	normal (>6h)	
Exclusion	Exclusions for ITI	
Criteria:	☐ Adults who have failed an adequate course of	
	ITI treatment in the past (at least 3	
	consecutive months of ITI terminated due	
	to documented failure)	
	☐ Adults who have had measurable inhibitor	YES / NO
	levels for 5+ years and who have never	
	undergone ITI treatment	
	☐ History of anaphylaxis or severe hypersensitivity to any component of	
	the chosen concentrate	
Age		N/A
Restriction:		,



Prescriber		N/A
Restrictions:		
Coverage	☐ Primary and Secondary Prophylaxis Approval = 12 months, unless	
Duration:	otherwise specified ☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately ☐ ITI Approval = 6 months	YES / NO
*Approvals require	e that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ANTIHEMOPHILIC FACTOR VIII (HUMAN) NON-MONOCLONAL ANTIBODY PURIFIED

Affected Medications: KOATE®-DVI

Covered Uses:	 □ All FDA-approved indications not otherwise excluded from Part B. □ Von Willebrand's Disease □ Acquired Hemophilia A. 	CONFIRMATION* YES / NO
Required Medical Information:	Von Willebrand's Disease − High Risk Prophylaxis □ For minor and major non-elective surgical Procedures □ DDAVP must have been deemed inadequate or inappropriate for prophylactic use, reason(s) must be documented Hemophilia A − Primary Prophylaxis □ Factor VIII levels <1% of normal (age 2+) Hemophilia A − Secondary Prophylaxis □ History of intracranial hemorrhage Factor □ Levels <1% and one or more joint bleeds □ Children under age 2 with Severe Hemophilia A (Factor VIII < 1% normal) who have had one or more joint bleeds, and for whom the benefits of prophylaxis outweigh the risk of central venous line use (if applicable) Hemophilia A − High Risk Prophylaxis □ For minor and major non-elective surgical Procedures	YES / NO
	Immune Tolerance Induction (ITI) ☐ Inhibitor titer <10 Bethesda Units before start of ITI therapy	
Appropriate Treatment Regimen & Other Criteria:	Primary and Secondary Prophylaxis: ☐ All trough level monitoring must be recorded in chart notes ITI ☐ may continue until inhibitor levels approach zero (<0.6 BU/mL) and factor levels show normal recovery (>66%) and/or FVIII half-life is normal (>6h)	YES / NO
Exclusion Criteria:	Exclusions for ITI ☐ Adults who have failed an adequate course of ☐ ITI treatment in the past (at least 3 ☐ consecutive months of ITI terminated due ☐ to documented failure) ☐ Adults who have had measurable inhibitor ☐ levels for 5+ years and who have never ☐ undergone ITI treatment ☐ History of anaphylaxis or severe hypersensitivity to any component of ☐ the chosen concentrate	YES / NO



Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Primary and Secondary Prophylaxis Approval = 12 months, unless	
Duration:	otherwise specified	YES / NO
	☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately	YES / NO
	☐ ITI Approval = 6 months	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



ANTIHEMOPHILIC FACTOR VIII/VWF COMPLEX Affected Medications: ALPHANATE®, HUMATE-P

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION*
	□ Acquired Von Willebrand's Disease	YES / NO
Required Medical Information:	Von Willebrand's Disease − High Risk Prophylaxis For minor and major non-elective surgical Procedures DDAVP must have been deemed inadequate or inappropriate for prophylactic use, reason(s) must be documented Hemophilia A − Primary Prophylaxis Factor VIII levels <1% of normal (age 2+) Hemophilia A − Secondary Prophylaxis History of intracranial hemorrhage Factor Levels <1% and one or more joint bleeds Children under age 2 with Severe Hemophilia A (Factor VIII < 1% normal) who have had one or more joint bleeds, and for whom the benefits of prophylaxis outweigh the risk of central venous line use (if applicable) Hemophilia A − High Risk Prophylaxis For minor and major non-elective surgical Procedures	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Primary and Secondary Prophylaxis: ☐ All trough level monitoring must be recorded in chart notes ☐ Monitor for signs and symptoms of thrombosis	YES / NO
Exclusion Criteria:	 ☐ History of anaphylaxis or severe hypersensitivity to any component of the chosen concentrate ☐ Acute thrombosis, embolism or symptoms of DIC 	YES / NO
Age		N/A
Restriction: Prescriber		N/A
Restrictions:		,
Coverage Duration:	 □ Primary and Secondary Prophylaxis Approval = 12 months, unless otherwise specified □ High Risk Prophylaxis Approval = until wound(s) healing appropriately 	YES / NO
*Approvals require	☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately that all bolded regions in the 'confirmation' column be documented in members.	·



ANTIHEMOPHILIC FACTOR VIII/VWF COMPLEX

Affected Medications: WILATE® Effective Date: 01/01/2014
Last Review Date: 11/14/2012

Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION*
	☐ Acquired Von Willebrand's Disease	YES / NO
Required	High Risk Prophylaxis	
Medical	☐ For minor and major non-elective surgical Procedures	
Information:	□ DDAVP must have been deemed inadequate or inappropriate for	YES / NO
	prophylactic use, reason(s) must be documented	
Appropriate	☐ Monitor for signs and symptoms of thrombosis	
Treatment		
Regimen &		YES / NO
Other Criteria:		
Exclusion	☐ History of anaphylaxis or severe hypersensitivity to any component of	
Criteria:	the chosen concentrate	YES / NO
	☐ Acute thrombosis, embolism or symptoms of DIC	123 / 113
Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Primary and Secondary Prophylaxis Approval = 12 months, unless	
Duration:	otherwise specified	YES / NO
	☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ANTIHEMOPHILIC FACTOR IX CONCENTRATES

Affected Medications: BENEFIX®, ALPHANINE® SD, MONONINE®, RIXUBIS

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION* YES / NO
Required Medical Information:	Hemophilia B – Primary Prophylaxis Factor IX levels < 1% of normal (age 2+) Hemophilia B – Secondary Prophylaxis History of intracranial hemorrhage Factor Levels < 1% and one or more joint bleeds Children under age 2 with Severe Hemophilia A (Factor VIII < 1% normal) who have had one or more joint bleeds, and for whom the benefits of prophylaxis outweigh the risk of central venous line use (if applicable) Hemophilia B - High Risk Prophylaxis For minor and major non-elective surgical procedures Hemophilia B - Immune Tolerance Induction (ITI) Evidence that the potential benefits of treating with ITI (taking into consideration low chance of success) outweighs the risks of nephritic syndrome and allergic reaction to Factor IX	YES / NO
Appropriate Treatment Regimen & Other Criteria: Exclusion Criteria:	Primary and Secondary Prophylaxis:	YES / NO



Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Primary and Secondary Prophylaxis Approval = 12 months, unless	
Duration:	otherwise specified	YES / NO
	☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately	125 / 110
	☐ ITI Approval: 6 months	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



ANTIHEMOPHILIC FACTOR VIIa CONCENTRATE Affected Medications: NOVOSEVEN® RT®

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION*
	□ Acquired Von Willebrand syndrome	YES / NO
Required Medical Information:	Hemophilia A or B with inhibitors – Secondary Prophylaxis □ Documentation of inhibitors AND one or more of the following criteria: □ History of intracranial hemorrhage □ Over age 2 with Severe Hemophilia A or B (Factor VIII or IX levels <1% of normal) and a history of one or more joint bleeds with risk of developing/progressing arthropathy □ Children under age 2 with Severe Hemophilia A or B, who have had one or more joint bleeds, and for whom the benefits of prophylaxis outweigh the risk of central venous line use (if applicable) All Indications: High Risk Prophylaxis □ For minor and major non-elective surgical procedures	YES / NO
Appropriate	Secondary Prophylaxis:	
Treatment Regimen &	☐ All trough level monitoring must be recorded in chart notes	YES / NO
Other Criteria:	☐ Monitor for signs and symptoms of thrombosis	
Exclusion Criteria:	 ☐ History of anaphylaxis, or severe hypersensitivity to any component of the chosen concentrate ☐ Acute thrombosis, embolism or symptoms of DIC 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	 □ Primary and Secondary Prophylaxis Approval = 12 months, unless otherwise specified □ High Risk Prophylaxis Approval = until wound(s) healing appropriately 	YES / NO
*Approvals require	l that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ANTI-INHIBITOR COAGULANT COMPLEX (HUMAN)

Affected Medications: FEIBA® NF Effective Date: 01/01/2014 Last Review Date: 11/14/2012 Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part B.	CONFIRMATION*
Corci cu oscsi		YES / NO
	☐ Acquired Hemophilia A	TES / NO
Required	☐ Must document inhibitor titer level for all indications	
Medical		
Information:	Hemophilia A or B with Inhibitors - High Risk Prophylaxis	
	☐ For minor and major non-elective surgical	
	□ Procedures	YES / NO
	Acquired Hemophilia A – High Risk Prophylaxis	·
	☐ For minor and major non-elective surgical procedures	
	☐ Must have documentation of inhibitor titers of 5 BU or greater	
	,	
Appropriate		
Treatment	☐ Monitor for signs and symptoms of thrombosis	
Regimen &		YES / NO
Other Criteria:		
Exclusion	☐ Absence of inhibitors/antibodies to Factor VIII or Factor IX	
Criteria:	□ Normal coagulation mechanisms	
	☐ History of anaphylaxis, or severe hypersensitivity to any component of	
	the chosen concentrate	YES / NO
	☐ Acute thrombosis, embolism or symptoms of DIC	
	Acade anombosis, embolish or symptoms of ble	
Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ High Risk Prophylaxis Approval = until wound(s) healing appropriately	YES / NO
Duration:		
		<u> </u>
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ARCALYST

Affected Medications: ARCALYST (Rilonacept)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical	□ Patient has a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold auto-inflammatory syndrome (FCAS) and	
Information:	Muckle-Wells syndrome (MWS).	YES / NO
Appropriate		
Treatment Regimen &		N/A
Other Criteria:		
Exclusion	☐ Active or chronic infection, concurrent therapy with other biologics.	YES / NO
Criteria:		ILS / NO
Age	☐ 12 years of age and older	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		IN/ A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	r's chart notes.



ARZERRA

Affected Medications: ARZERRA (ofatumumab)

Effective Date: <u>07/01/2014</u>
Last Review Date: <u>06/11/2014</u>
Part D: No Part B: Yes (J9302)

Member:	DOB: ID#: Provider:	Dx:
Covered Uses:	☐ All FDA-approved indications not otherwise excluded from	1
Required Medical Information:	 □ Previous therapies tried/failed □ Hepatitis B screening □ Karnofsky Performance Status OR ECOG performance statu 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Untreated CLL: 300 mg initial dose, followed by up to 12 28 of 1,000 mg Refractory CLL: 300 mg initial dose, followed by 11 28-day of 2,000 mg Continuation of therapy requires documentation of responsible therapy 	cycles of YES / NO
Exclusion Criteria:	 Hepatitis B (current or historical, unless being managed in with GI, ID, or hepatologist) Live vaccination within 4 weeks of treatment Re-induction with Arzerra (max approval is 12 cycles) Karnofsky performance score less than 50% ECOG performance status 3 or higher 	YES / NO
Age Restriction:	□ 18 years and older	YES / NO
Prescriber Restrictions:	□ Oncologist	YES / NO
Coverage Duration:	☐ Approval = 6 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be docume	nted in member's chart notes.



ASPARAGINASE, PERASPARAGASE

Affected Medications: ERWINAZE (Aparaginase Erwinia Chrysanthemi), ONCASPAR (Pegaspargase)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ For use of Erwinaze (Aparaginase Erwinia Chrysanthemi): documentation of failure or contraindication to use of Oncaspar (Pegaspargase) must be provided.	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:		N/A
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified. that all bolded regions in the 'confirmation' column be documented in men	YES / NO



AUBAGIO

Affected Medications: AUBAGIO (Teriflunomide)

Effective Date: 06/01/2013
Last Review Date: 4/10/2012
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required Medical Information:	 ☐ Use in Multiple Sclerosis (MS), patient has a relapsing form of MS. ☐ Baseline transaminase and bilirubin levels documented. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 □ For use in MS, patient has a relapsing form of MS and patient has tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), or glatiramer acetate (Copaxone). □ Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif) or glatiramer acetate (Copaxone) can be made if the patient is unable to administer injections due to dexterity issues or visual impairment. □ Patients who have tried natalizumab (Tysabri) for MS and have a relapsing form of MS will receive authorization, they are not required to try an interferon beta product or glatiramer acetate. □ Liver function tests will be monitored at least monthly for 6 months once treatment is initiated. □ Female patients should have a negative pregnancy test prior to therapy. 	YES / NO
Exclusion Criteria:	 □ Patients with known liver disease should not begin treatment with teriflunomide. □ Concurrent use of Avonex, Betaseron, Extavia, Rebif, Copaxone, Tysabri, or fingolimod (Gilenya). 	YES / NO
Age	☐ Adults	YES / NO
Restriction:		
Prescriber Restrictions:	☐ Prescribed by a neurologist or an MS specialist.	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



AVONEX

Affected Medications: AVONEX (interferon beta-1a)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Has relapsing form of MS (eg. relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses) OR □ first clinical episode of MS with MRI scan that demonstrated features consistent with a diagnosis of MS (i.e., multifocal white matter disease). 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Approve for patients already started on Avonex. For patients not currently on Avonex, approve if the patient has previously tried Betaseron, Copaxone, or Rebif. 	YES / NO
Exclusion Criteria:	☐ Concurrent use of any of the following medications: interferon-beta therapy (Betaseron, Extavia, or Rebif), Copaxone, mitoxantrone, Tysabri, or fingolimod (Gilenya).	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	☐ Prescribed by or after consultation with a neurologist or an MS specialist.	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



PART B VERSUS PART D (B vs D)

Affected Medications: ABELCET, ABRAXANE, ACETYLCYST, ACYCLOVIR SOL, ADRIAMYCIN, ALBUTEROL, ALIMTA, ALKERAN, AMBISOME, AMIFOSTINE, AMINOSYN, AMPHOTERICIN, ARRANON, ARZERRA, ASTRAMORPH, ATGAM®, AVASTIN, AZASAN®, AZATHIOPRINE, BICNU, BLEOMYCIN, BROVANA, BUDESONIDE, BUSULFEX, CALCIJEX®, CALCITRIOL, CAMPATH, CAMPTOSAR, CARBOPLATIN, CARNITOR®, CELLCEPT®, CERUBIDINE, CESAMET®, CISPLATIN, CLADRIBINE, CLINIMIX, CLINISOL, CLOLAR, COLISTIMETH, COSMEGEN, CROMOLYN, CUBICIN®, CYCLOPHOSPHAMIDE, CYCLOSPORINE, CYCLOSPORINE MODIFIED, CYTARABINE, CYTOVENE, DACARBAZINE, DACOGEN, DAUNORUBICIN, DECAVAC, DEPO-PROVERA, DEXRAZOXANE, DOCETAXEL, DOXIL, DOXORUBICIN, DRONABINOL, DUONEB, DURAMORPH, ELITEK, ELLENCE, ELOXATIN, ELSPAR, EMEND®, ENGERIX-B, EPIRUBICIN, ERBITUX, ETOPOPHOS, ETOPOSIDE, FASLODEX, FIRMAGON, FLUDARABINE, FLUOROURACIL, GANCICLOVIR, GEMCITABINE, GEMZAR, GENGRAF, GRANISETRON HCL, GRANISOL, HALAVEN, HECTOROL®, HEPARIN SODIUM, HEPATAMINE, HEPATASOL, HERCEPTIN, HUMULIN R INJ U-500, HYCAMTIN, HYDROMORPHONE INJ, IDAMYCIN, IDARUBICIN, IFEX, IFOSFAMIDE, IMURAN®, INTRALIPID, INTRON-A, IPRATROPIUM, IRINOTECAN, ISTODAX, IXEMPRA KIT, KEPIVANCE, LEUCOVORIN, LEVALBUTEROL NEB, LEVOCARNITINE, LIPOSYN, MELPHALAN, MESNA, MESNEX, METHOTREXATE, MIACALCIN®, MITOXANTRONE HCL, MUSTARGEN, MYCOPHENOLATE MOFETIL, MYFORTIC®, NEBUPENT, NEORAL®, NEPHRAMINE, NIPENT, NULOJIX, ONDANSETRON HCL, ONDANSETRON ODT, ONTAK, OXALIPLATIN, PACLITAXEL, PAMIDRONATE DISODIUM, PENTOSTATIN, PERFOROMIST, PREMASOL, PROCALAMINE, PROGRAF®, PROLEUKIN, PROSOL, PULMICORT, PULMOZYME®, RAPAMUNE®, RECOMBIVAX HB, SANDIMMUNE®, SIMULECT®, TACROLIMUS, TAXOTERE, TET/DIP TOX INJ, THIOTEPA, THYMOGLOBULIN®, TOBI®, TOPOSAR, TOPOTECAN, TORISEL, TPN, TRAVASOL, TREANDA, TREXALL®, TRISENOX, TROPHAMINE, TWINRIX, UVADEX, VANCOMYCIN HCL, VECTIBIX, VELCADE, VIDAZA, VINBLASTINE, VINCASAR, VINCRISTINE, VINORELBINE, ZANOSAR, ZEMPLAR®, ZINECARD, ZORTRESS®

Effective Date: 01/01/2014
Last Review Date: 06/12/2013
Part D. Voc. Part B. Voc.

Part D: Yes Par	τ Β:	: Yes	
Covered Uses:		This drug may be covered under Medicare Part B or D depending upon	CONFIRMATION*
		the circumstances.	
		Information may need to be submitted describing the use and setting	YES / NO
		of the drug to make the determination.	
Required			
Medical			N/A
Information:			
Appropriate		For ESRD agents,	
Treatment		☐ Deny as Part D, If Prescriber receive a monthly capitation payment	
Regimen &		to manage ESRD patients' care AND the drug prescribed is ESRD-	
Other Criteria:		related.	
		☐ Approve as Part D and direct reviewer to issue a 70-ESRD	
		OVERRIDE, If the Prescriber does NOT receive a monthly	YES / NO
		capitation payment to manage ESRD patients' care and/or the	·
		drug prescribed is NOT ESRD-related.	
		☐ if the pharmacy determines that the prescription for a drug that	
		may be ESRD-related was written by any of the following: dentist;	
		chiropractor; gynecologist; ophthalmologist; podiatrist; or	
		hospital emergency room prescriber, then the plan should accept	



	this information from the pharmacy to establish that the	
	prescriber does not receive a monthly capitation payment for	
	managing the ESRD patient's care and provide an override to the	
	ESRD PA edit.	
Exclusion		N/A
Criteria:		IN/A
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage		NI/A
Duration:		N/A
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.		



POLICY NAME: BETASERON

Affected Medications: BETASERON (interferon beta-1b)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Relapsing form of MS (eg. relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses) OR first clinical episode of MS with MRI scan that demonstrated features consistent with a diagnosis of MS (i.e., multifocal white matter disease). 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:	☐ Concurrent use of any of the following medications: interferon-beta therapy (Extavia, or Rebif), Copaxone, mitoxantrone, Tysabri, or fingolimod (Gilenya).	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	☐ Prescribed by or after consultation with a neurologist or an MS specialist.	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	ber's chart notes.



POLICY NAME:BONIVA INJECTION

Affected Medications: BONIVA INJECTION (ibandronate injection)

Member:	DOB: ID#: Provider:	Dx:
Covered Uses:	 □ All FDA-approved indications not otherwise excluded from Part D. □ Treatment of osteoporosis in women (non PMO). □ Hypercalcemia of malignancy. □ Prevention of postmenopausal osteoporosis. □ Treatment of bone metastases in patients with solid tumor (eg, breast cancer, prostate cancer). □ Osteoporosis disorder related to organ transplantation. 	CONFIRMATION* YES / NO
Required Medical		N/A
Information:		·
Appropriate Treatment Regimen & Other Criteria:	All osteoporosis uses (treatment or prevention), approve if patient has tried one oral bisphosphonate-containing product AND they had an inadequate response (determined by prescribing physician) or intolerability to oral bisphosphonate OR patient cannot take an oral bisphosphonate-containing product due to inability to swallow unable to remain in an upright position for designated period of time following oral bisphosphonate administration patient has pre-existing GI medical condition in which IV therapy is preferred over oral therapy, OR patient has a chronic, complex medication regimen in which oral bisphosphonate may compromise therapy (as determined by prescribing physician) OR patient is currently receiving ibandronate injection for a covered use. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related	YES / NO
	condition.	
Exclusion	☐ Use in the management of multiple myeloma patients	
Criteria:	□ patients with osteolytic lesions of multiple myeloma	YES / NO
	□ treatment of osteopenia or the prevention of bone loss in cancer	



	patients	
	□ Paget's disease of bone	
	□ osteogenesis imperfecta, or prevention or treatment of glucocorticoid-	
	induced osteoporosis (GIO)	
	☐ Coverage is not recommended for circumstances not listed in the	
	Covered Uses.	
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



BOTOX

Affected Medications: BOTOX (onabotulinumtoxinA)

Member:		DOB:	ID#:	Provider:	_ Dx:
Covered Uses:		All FDA-approved inc	dications not other	wise excluded from Part D.	CONFIRMATION*
		Plus Achalasia.		mise excluded from tare 2.	
		Anal Fissure.			
		Benign Prostatic Hye	rplasia (BPH).		
		Chronic facial pain/p	•	TMJ dysfunction.	YES / NO
		Chronic low back pai		•	
		Headache (migraine,	chronic tension HA	A, whiplash, chronic daily HA).	
		Palmar/plantar and f			
		Myofascial pain.			
		Salivary hypersecreti	on.		
				oke, brain injury, spinal cord	
	_	injury, MS, hemifacia	al spasm).		
		Essential tremor.		and a state of the self-self-self-self-self-self-self-self-	
		anismus).	cervical (eg, focal d	ystonias, tardive dystonia,	
		Bladder/voiding/ure	thral dysfunction.		
		Frey's syndrome (gus	statory sweating).		
		Ophthalmic disorder	s (eg, esotropia, ex	otropia, nystagmus, facial nerve	
		paresis).			
		Speech/voice disorde	ers (eg, dysphonias).	
		Tourette's syndrome	!.		
		Additional indication	s will be evaluated	by a pharmacist and/or a	
		physician on a case-b	y-case basis.		
Required	Ch	ronic Migraine Proph	vlaxis		
Medical				least 15 headaches per month,	
Information:		·	· ·	e to at least 8 weeks of oral	
		migraine preventativ			
		•	• •	tion cycle): 50% reduction in	
		headache frequency			YES / NO
	Pr	imary Axillary Hyperh	_		
				nts (such as topical aluminum	
		chloride solution or i	ontophoresis) with	out adequate relief.	



	Urinary incontinence associated with a neurologic condition (eg, spinal	
	cord injury, multiple sclerosis):	
	□ patient had an inadequate response to or is intolerant of an	
	anticholinergic medication.	
Appropriate	☐ Patient has been educated about potential spread of toxin effects (eg,	
Treatment	breathing and swallowing difficulties)	WEG / NO
Regimen &		YES / NO
Other Criteria:		
Exclusion	☐ Use in the management of cosmetic uses (eg, facial rhytides, frown	
Criteria:	lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face	
	and neck rejuvenation, platsymal bands, rejuvenation of the peri-	
	orbital region),	
	□ allergic rhinitis	YES / NO
	□ gait freezing in Parkinsons disease	
	□ vaginismus	
	□ interstitial cystitis	
	☐ Crocodile tears syndrome	
Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Chronic migraine, initial: 12 wks; subsequent: 12 months	YES / NO
Duration:	☐ All other indications: approval = 12 months	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



BUPRENORPHINE/NALOXONE FILM

Affected Medications: SUBOXONE FILM (BUPRENORPHINE/NALOXONE)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved in	ndications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:	□ no dependence on a □ free from significar	l in a program of sup alcohol or benzodiaz nt untreated psychiat ne must be ≤ 102 tak	epines cric comorbidities.	YES / NO
Exclusion Criteria:	☐ Use in the manager	nent of pain in non-c	ppioid dependent patients.	YES / NO
Age Restriction:	Opioid Dependence: □ Pt ≥ 16 years			YES / NO
Prescriber Restrictions:	☐ Prescriber must be requirements.	certified to prescribe	Suboxone per DATA 2000	YES / NO
Coverage Duration:	☐ Initial Approval = 3 ☐ Subsequent Approv			YES / NO
*Approvals require	that all bolded regions in	the 'confirmation' o	column be documented in me	mber's chart notes.



CAPRELSA

Affected Medications: CAPRELSA® (vandetanib)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ Symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Hypocalcemia, hypokalemia, or hypomagnesemia must be corrected prior to Caprelsa administration. ECG should be obtained to monitor the QT at baseline, then 2 to 4 weeks after starting treatment or dose reduction/interruption, then 8 to 12 weeks after starting treatment or dose reduction/interruption, then every 3 months thereafter. ECG must be monitored more frequently if patient is receiving any drugs known to prolong the QT interval (e.g., anti-arrhythmic drugs, chloroquine, clarithromycin, dolasetron, granisetron, haloperidol, methadone, moxifloxacin, pimozide.) 	YES / NO
Exclusion Criteria:	□ Long QT syndrome.	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless noted otherwise specified.	YES / NO



CHANTIX

Affected Medications: CHANTIX (varenicline)

Member:		_ DOB:	ID#:	Provide	er:	_ Dx:
Covered Uses:	□ All	FDA-approved i	ndications not oth	erwise excluded fro	om Part D.	CONFIRMATION* YES / NO
Required Medical Information:	inc	luding the use o	of Chantix, has resu after a 90 day sup	ntix, the patient's trulited in smoking cestiles ply of Chantix has b	ssation.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	in b	ehavior, hostilit	ty, agitation, depr	ychiatric symptoms essed mood, and su and attempted suid	iicide related	N/A
Exclusion Criteria:						N/A
Age Restriction:						N/A
Prescriber Restrictions:						N/A
Coverage Duration: *Approvals require	□ Sub	nths	roval = 12 weeks a	dditional , max of 6		YES / NO



CIMZIA

Affected Medications: CIMZIA (certolizumab)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	indications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	notes within the m Documentation of For treatment of R Rheumatoid Arthri CCP) OR Rheumato For Negative laten interferon gamma request. OR For positive latent treatment for LTBI	nost recent 6 months. complete and current A: Laboratory test multis: Anti-Cyclic Citrull old Factor (RF). It TB screening with earlease assay (e.g., Complete TB, patient must have be the patitis B (HBV) in the patitis B (HBV) in the patitis B (HBV) in the complete TB, patient must have the patitis B (HBV) in the patiti	t treatment course required. ust confirm diagnosis of inated Peptide Antibody(anti- ither a TB skin test or an IFT-GIT, T-SPOT.TB) prior to e completed or is receiving fection, HBV has been ruled out	YES / NO
Appropriate Treatment Regimen & Other Criteria:	(hydroxychloroqui sulfasalazine) AND □ Patient has failed a agent [abatacept (adalimumab (Humcertolizumab(Cimz) Adult Crohn's Disease Induce remission: □ Approve if patient if corticosteroids a if patient is curren Maintain remission: □ Approve if patient induce response/recertolizumab pego	at least 12 weeks of the least 12 weeks	oids or of certolizumab pegol to 2 weeks of therapy with	YES / NO



	□ i	if the patient has not received certolizumab pegol for induction of	
	r	remission then authorize if patient has tried azathioprine, 6-	
	r	mercaptopurine, or MTX or if patient has tried infliximab or	
	a	adalimumab.	
Exclusion		Active infection (including TB)	
Criteria:		Concurrent use of: abatacept (Orencia), rituximab(Rituxin),	
	t	tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel),	YES / NO
	i	infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi)	
		Use for the management of plaque psoriasis.	
Age		≥ 18 years old	YES / NO
Restriction:			
Prescriber			N/A
Restrictions:			
Coverage		Initial RA, approval = 12 months	VEC / NO
Duration:		Initial CD, approval = 3 months	YES / NO
		Subsequental approval = 12 months	
*Approvals require	that a	all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



POLICY NAME: C1 INHIBITOR

Affected Medications: BERINERT, CINRYZE

Effective Date: 10/01/2009 Last Review Date: 06/10/2009 Part D: No Part B: Yes

Covered Uses:	All FDA-approved indications not otherwise excluded from Part D. CONFIRMA	
	☐ Hereditary Angiodema	YES / NO
Required Medical Information:	 □ FDA approved Indication must be documented in the member's chart notes within the most recent 6 months. □ Documentation of complete & current treatment course required. □ Number of HAE attacks per month must be >= 2. □ Laboratory confirmation of diagnosis: (the following levels must be documented) □ C4 antigenic level: □ C1-inhibitor antigenic level: □ C1-inhibitior functional level:	YES / NO
	☐ Enrollment in Cinryze Solutions Support program suggested: (877) 945-1000	
Appropriate Treatment Regimen & Other Criteria:	 Initial approval requires documented failure, intolerance, or clinical rationale for avoidance to the following: Androgens: danazol, stanozolol, oxandrolone, oxymetholone, tibolone, or methyltestosterone. Subsequent approval requires documentation of treatment success. 	YES / NO
Exclusion Criteria:	☐ Coverage is not recommended for circumstances not listed under Covered Uses.	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	 Must be prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. 	YES / NO
Coverage Duration:	☐ Initial approvals = 3 months.☐ Subsequent approvals = 12 months.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



COMBINATION BETA2-AGONIST/CORTICOSTEROID INHALERS

Affected Medications: ADVAIR Effective Date: 01/01/2014 Last Review Date: 09/23/2012

Part D: Yes Part B: No

Covered Uses:	All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	COPD.	YES / NO
Required	For Asthma , documentation of current level of control per NIH	
Medical	guidelines (Well Controlled, Not Well Controlled, Poorly Controlled).	WEG / NO
Information:	For COPD , documentation of GOLD Staging (Stage I - IV) and PFT	YES / NO
	results.	
Appropriate	For Asthma, failed:	
Treatment	☐ inhaled corticosteroid monotherapy	
Regimen &	OR	
Other Criteria:	☐ ≥ 2 other common treatments (cromolyn, leukotriene receptor	
	antagonist, nedocromil, theophylline)	
	OR	
	□ poorly controlled asthma necessitating urgent treatment with	
	combination product.	
	☐ Patients with well controlled asthma for 3 months or longer,	VEC / NO
	should step-down to ICS monotherapy or other common	YES / NO
	treatments per NIH guidelines.	
	For COPD, failed:	
	□ Long Acting Beta Agonist monotherapy	
	OR	
	□ anticholingeric bronchodilator (Spiriva, Atrovent, Combivent)	
	OR	
	$\hfill \Box$ poorly controlled COPD necessitating urgent treatment with	
	combination product.	
Exclusion	Treatment of symptoms associated with a current rhinovirus	
Criteria:	infection/cough associated with a current episode of the common	
	cold.	
	Treatment of chronic cough due to GERD, NAEB, bronchiolitis,	
	bronchiectasis, ACE-Inhibitor induced cough, whooping cough,	YES / NO
	pertussis, psychogenic cough, habit cough, tic cough.	123 / 140
	Treatment of symptoms due to an acute respiratory infection (eg,	
	bronchitis, sinusitis, pneumonia).	
	Coverage is not recommended for circumstances not listed in the	
	Covered Uses.	
Age		N/A



Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Initial approval: 6 months.	YES / NO
Duration:	☐ Subsequent approval: 12 months, unless otherwise specified.	
*Approvals require to	hat all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: COPAXONE

Affected Medications: COPAXONE (glatiramer)

Covered Uses:		All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required		Relapsing-remitting MS OR	
Medical		first clinical episode of MS with MRI scan that demonstrated features	YES / NO
Information:		consistent with a diagnosis of MS (i.e., multifocal white matter disease).	
Annuantiata		uisease).	
Appropriate			21/2
Treatment			N/A
Regimen &			
Other Criteria:			
Exclusion		Concurrent use of any of the following medications: interferon-beta	VEC. / NO
Criteria:		therapy (Avonex, Betaseron, Extavia, or Rebif) or mitoxantrone.	YES / NO
Age			N/A
Restriction:			
Prescriber		Prescribed by or after consultation with a neurologist or an MS	YES / NO
Restrictions:		specialist.	
Coverage		Approval = 12 months, unless otherwise specified.	YES / NO
Duration:			
*Approvals require	that	t all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



CYRAMZA

Affected Medications: CYRAMZA (ramucirumab)

Effective Date: <u>07/01/2014</u>
Last Review Date: <u>06/11/2013</u>
Part D: No Part B: Yes (J9999)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved	indications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	platinum-containii Disease progressic Docetaxel	ng chemotherapy	ifter fluoropyrimide or ring: Irinotecan, Paclitaxel, performance status.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	□ 8 mg/kg every two □ Re-approval: recer is responding to the	nt scan (within 3 mont	ths) demonstrating that patien	t YES / NO
Exclusion Criteria:		ertension nance score less than ! e status 3 or higher	50%	YES / NO
Age Restriction:	☐ 18 years and older	r		YES / NO
Prescriber Restrictions:	□ Oncologist			N/A
Coverage Duration:		ths, unless otherwise	•	YES / NO
*Approvals require	that all bolded regions	in the 'confirmation'	column be documented in mer	nber's chart notes.



DIGOXIN

Affected Medications: LANOXIN 0.25mg (digoxin 0.25mg)

Effective Date: <u>01/01/2014</u> Last Review Date: 05/22/2013

Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required	☐ Serum digoxin level within 12 months (or 14 -21 days after dose	
Medical	increase or initiation)	YES / NO
Information:		
Appropriate	☐ Serum digoxin level 0.5 to 1.0 ng/ml (or clinical justification for higher	
Treatment	serum target) AND diagnosis of heart failure or atrial fibrillation.	
Regimen &		YES / NO
Other Criteria:		
Exclusion	☐ Significant sinus or atrioventricular block (unless on permanent	VEC / NO
Criteria:	pacemaker)	YES / NO
Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



EMSAM

Affected Medications: EMSAM (selegiline transdermal system)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Clinical diagnosis of major depressive disorder AND □ Patient not responsive to ≥ two (2) of the following antidepressants with documented trials of clinically sufficient doses and duration of six weeks each or longer: □ selective serotonin reuptake inhibitors (SSRI), □ serotonin/norepinephrine reuptake inhibitors (SNRI), □ bupropion, □ mirtazapine, or □ tricyclic/tetracyclic antidepressants. OR □ Clinical diagnosis of major depressive disorder for those patients who are unable to take any oral preparations (including commercially available liquid antidepressants). □ For requests over 6 mg/24 hours, patient must agree to adhere to a tyramine restrictive diet. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:	 □ Pheochromocytoma □ Concurrent use of the following medications: dextromethorphan or St. John's Wort. 	YES / NO
Age		N/A
Restriction: Prescriber Restrictions:	☐ Psychiatrist or receiving input from a psychiatry practice	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO



ENBREL

Affected Medications: ENBREL (etanercept)

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved	indications not other	vise excluded from Part D.	CONFIRMATION*
	□ Plus Acute or chro	onic graft versus host o	lisease (GVHD).	YES / NO
Required Medical			nented in the member's chart	
Information:		nost recent 6 months.		
Imormation.		•	t treatment course required.	
		•	ust confirm diagnosis of	
		•	nated Peptide Antibody(anti-	
	CCP) OR Rheumat	• •	there TD ekin test or an	
	_	_	ther a TB skin test or an	YES / NO
	Enbrel request. O		FT-GIT, T-SPOT.TB) prior to	
	•		e completed or receiving	
	treatment for LTB	•	completed of receiving	
			fection, HBV has been ruled out	
	or treatment has	, , , , , , , , , , , , , , , , , , , ,		
Appropriate	Rheumatoid Arthritis	(RA), Juvenile Idiopat	hic Arthritis (JIA)	
Treatment	□ pt tried ≥ 2 oral D	MARDs for ≥ 12wks (h	ydroxychloroquine,	
Regimen &	leflunomide, sulfa	salazine, minocycline,	methotrexate) OR	
Other Criteria:	□ pt has failed at lea	ast 12 weeks of therap	y of another biologic agent	
	[abatacept (Oreno	cia), rituximab(Rituxin)	, tocilizumab(Actemra),	
	adalimumab (Hun	nira), entanercept(Enb	rel), infliximab(Remicade),	
	certolizumab(Cim	zia), golimumab(Simp	oni)]	
	Psoriatic Arthritis (Ps	Α)		YES / NO
	-	-	droxychloroquine, leflunomide,	120 / 110
		ocycline, methotrexat		
	Plaque psoriasis (PP)			
	□ pt has tried ≥ 1 sy	stemic therapy (metho	otrexate, cyclosporine,	
	isotretinoin) OR p	hototherapy (UVB, PU	VA)	



	GVHD	
	☐ Approve if managed by a transplant center AND has tried or currently is receiving one conventional GVHD treatment (high-dose SC, CSA, tacrolimus, etc.)	
Exclusion	☐ Active infection (including TB).	
Criteria:	☐ Concurrent use with abatacept (Orencia), rituximab(Rituxin),	
	tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel),	
	infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi).	
	☐ Intra-articular injection of etanercept.	
	☐ Use in the management of alopecia areata, alopecia totalis, alopecia	
	universalis, asthma, Crohn's disease, dermatomyositits/polymyositis,	
	inclusion body myositis, Graves ophthalmopathy, hepatitis C, alcoholic	
	hepatitis, idiopathic pulmonary fibrosis, immune-mediated	YES / NO
	cochleovestibular disorders, immune thrombocytopenic purpura,	
	myelodysplastic syndrome, prevention of peri-prosthetic osteolysis,	
	primary sclerosing cholangitis, recurrent spontaneous pregnancy loss,	
	ocular sarcoidosis, pulmonary sarcoidosis, sciatica, Sjogren's syndrome,	
	Takayasu's arteritis, Wegener's granulomatosis, cancer	
	anorexia/weight loss syndrome, new-onset diabetes mellitus type 1,	
	keloids, and Alzheimer's disease.	
	☐ Positive test for tuberculosis, active HZV, HCV or HBV.	
Age	□ RA, PsA, PP, AS: Adults.	YES / NO
Restriction:		
Prescriber	☐ PP: in consultation with a dermatologist.	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	e that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



POLICY NAME: ENTERAL NUTRITION

Affected Medications: ENTERAL NUTRITION

Effective Date: <u>08/01/2011</u> Last Review Date: <u>06/8/2011</u> Part D: No Part B: Yes

Covered Uses:	All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Nutritional Deficiency identified by one of the following: Total protein < 5.6g/dl or albumin < 3.4g/dl, OR Recent assessment by MD / RD indicating caloric/protein intake is not obtainable through regular, liquefied or purified foods. In the absence of Nutritional Deficiency, prolonged history of malnutrition (ie. Years) and both of the following:	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Registered Dietician assessment in the past 3 months indicates sufficient caloric/protein intake is not obtainable through regular, liquefied or pureed foods (i.e., liquefied/pureed foods have been tried and failed)	YES / NO
Exclusion Criteria:	☐ Able to obtain formula type or qty required through other programs (i.e. WIC)	YES / NO
Age Restriction:	☐ See 'Required Medical Information'	YES / NO
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Authorization = 12 months, unless otherwise specified. Part all bolded regions in the 'confirmation' column be documented in member	YES / NO



ERIVEDGE

Affected Medications: ERIVEDGE (vismodegib)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required		
Medical		N/A
Information:		14/7
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion		N/A
Criteria:		IN/A
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise specified	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ESTROGENS

Affected Medications: ACTIVELLA, ALORA, CENESTIN, CLIMARA, CLIMARA PRO PATCH, COMBIPATCH, DIVIGEL, ELESTRIN PATCH, ENJUVIA, ESTRACE TAB, ESTRADIOL TAB, ESTRADIOL PATCH, ESTRODIOL-NORETHINDRONE TAB, ESTROPIPATE TAB, EVAMIST SOL, JINTELI TAB, MENEST TAB, MONOSTAR PATCH, MINIVELLE PATCH, PREFEST TAB, PREMARIN, PREMPRO, VIVELLE-DOT

Effective Date: <u>01/01/2014</u> Last Review Date: <u>05/22/2013</u>

Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Patient has been educated about increased risks of DVT, pulmonary embolism (PE), stroke and myocardial infarction (MI) in postmenopausal women. Patient has been educated about cancer risk and increased risk of developing probable dementia while on systemic hormone replacement therapy. A yearly evaluation of need is completed discussing need for hormone replacement therapy. 	YES / NO
Exclusion Criteria:		N/A
Age Restriction:	□ > 65 years of age	YES / NO
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



EXJADE

Affected Medications: Exjade (deferasirox)

Member:	DOB: ID#: Provider:	_ Dx:
Covered Uses:	All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	Diagnosis of transfusion-dependent anemia with chronic iron overload due to blood transfusions (transfusional hemosiderosis). Pretreatment serum ferritin level within the last 60 days of at least 1000 mcg/L Baseline and then monthly, or more frequently as indicated, monitoring of serum ferritin, serum creatinine/creatinine clearance, serum transaminases, bilirubin, and urinalysis (urine protein). On renewal, for patients with serum ferritin below 500 mcg/L, temporary interruption of Exjade therapy should be considered. For patients with persistent or severe increases in creatinine or liver function tests, the prescriber will consider dose modification or interruption of treatment. Diagnosis of chronic iron overload in patients 10 years and older with nontransfusion-dependent thalassemia syndromes and with a liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L on at least 2 measurements 1 month apart.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Exjade should not be used with Desferal (deferoxamine).	YES / NO
Exclusion Criteria:	CrCl < 40 mL/min. Severe hepatic impairment. Platelet count <50,000/mcL. Patient with poor performance status and high-risk myelodysplastic syndrome (MDS) or advanced malignancies.	YES / NO
Age Restriction:	≥ 2 years of age	YES / NO
Prescriber Restrictions:	Hematologist	YES / NO



Coverage	☐ Authorization will be for 12 months, unless otherwise specified.	YES / NO	
Duration:			
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.			



EXTAVIA

Affected Medications: Extavia (interferon beta-1b)

Covered Uses:	All FDA-approved indi	ications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	relapsing MS, or secon	(eg. relapsing-remitting MS, progressive- ndary progressive MS with relapses) OR f MS with MRI scan that demonstrated features nosis of MS (i.e., multifocal white matter	YES / NO
Appropriate Treatment Regimen & Other Criteria:	For patients requestin tried Betaseron, Copa	ng Extavia, approve if the patient has previously exone, or Rebif.	YES / NO
Exclusion Criteria:	•	y of the following medications: interferon-beta or Rebif), Copaxone, mitoxantrone, Tysabri, or	YES / NO
Age Restriction:			N/A
Prescriber Restrictions:	Prescribed by or after specialist.	consultation with a neurologist or an MS	YES / NO
Coverage Duration:	Approval = 12 months	s, unless otherwise specified.	YES / NO
*Approvals require	nt all bolded regions in th	he 'confirmation' column be documented in memb	er's chart notes.



EYLEA

Affected Medications: EYLEA® (aflibercept)

Member:		_ DOB:	ID#:	Provider:	Dx:
Covered Uses:	□ All	FDA approved ir	ndications not other	wise excluded by from Part [O CONFIRMATION* YES / NO
Required Medical Information:		e following: o Intravit	treal Avastin (bevaci	, please call 541-330-4999 or subm	YES / NO
Appropriate Treatment Regimen & Other Criteria:	□ Sub	sequent approv	val requires docume	ntation of treatment success	YES / NO
Exclusion Criteria:	□ Evi	dence of a curre	nt ocular or periocu	lar infection	YES / NO
Age Restriction:					N/A
Prescriber Restrictions:	□ Ор	hthalmologist			YES / NO
Coverage Duration:	□ Арј	oroval = 6 month	hs		YES / NO
*Approvals require	that all b	oolded reaions ii	n the 'confirmation'	column be documented in n	nember's chart notes.



POLICY NAME: FERRIPROX

Affected Medications: Ferriprox (Deferiprone)

Covered Uses:	☐ All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required		
Medical		N/A
Information:		
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion	□ Evidence of a current ocular or periocular infection	VEC / NO
Criteria:		YES / NO
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise specified	VEC / NO
Duration:		YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



FORTEO

Affected Medications: FORTEO (teriparatide)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved inc	dications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ For osteoporosis, do indicating Major frac		ore ≤ to -2.5 or FRAX Score	N/A
Appropriate Treatment Regimen & Other Criteria:	than 30 mL/min) OR chronic kidney disease if the patient has mu T-scores less than -3. Documentation of ca Therapy will be discontreatment.	phonate (eg, alendronic acid [Reclast]), overe renal impairmense, OR altiple vertebral fractions.5	onate, risedronate, OR Int (eg, creatinine clearance less tures in the setting of vertebral of treatment required. Cime total of 24 months of	YES / NO
Exclusion Criteria:	prior radiation thera malignancy, bone me bone disease other t prevention of osteop	epiphyses (ie, pediat py involving the ske etastases, pre-existi than osteoporosis, coorosis (women and	ric or young adult patient), leton, history of a skeletal ng hypercalcemia, metabolic oncurrent bisphosphonate use,	YES / NO
Restriction:	open epiphyses	used in pediatric p	attents of young addits with	
Prescriber Restrictions:				YES / NO
Coverage Duration: *Approvals require	☐ Approval = 12 month		specified.	YES / NO
Approvais require	triat air bolueu regions in	are commination t	oranni de adcamentea ili iliend	ci 3 cilait Hotes.



GAZYVA

Affected Medications: GAZYVA (obinutuzumab)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>12/11/2013</u>
Part D: No Part B: Yes (J9999)

Member:		DOB:	ID#:	Provider:	Dx:	
Covered Uses:	□ All	FDA-approved i	ndications not other	wise excluded from Part D.	CONFIRMAT YES / N	
Required Medical Information:		-	•	emia s screening (HBsAG and ant	YES / N	IO
Appropriate Treatment Regimen & Other Criteria:	□ Co	mbination with o	chlorambucil		YES / N	IO
Exclusion Criteria:					N/A	
Age Restriction:	□ Ag	e > 18 years			YES / N	Ю
Prescriber Restrictions:	□ Or	ncologist			YES / N	Ю
Coverage Duration:	□ Ар	proval = 12 mon	ths, unless otherwis	e specified.	YES / N	10
*Approvals require	that all	bolded regions i	n the 'confirmation'	column be documented in r	member's chart notes.	



GILENYA

Affected Medications: GILENYA (fingolimod)

Member:		DOB:	ID#:	Provider:	D:	x:
Covered Uses:	□ AI	l FDA-approved indi	cations not otherv	rise excluded from Part D.	СО	NFIRMATION* YES / NO
Required Medical Information:	□ Fo	or use in Multiple Sc	lerosis (MS), patiei	it has a relapsing form of I	MS.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	into su gla gla (A ca de	terferon beta-1a int bcutaneous (Rebif), atiramer acetate (Co ceptions to having to vonex, Betaseron, E in be made if the pa exterity issues or vis atients who have tri	ramuscular (Avone interferon beta-1 opaxone). tried an interferon extavia, or Rebif) or tient is unable to a ual impairment. ed natalizumab (Twill receive author	rm of MS and patient has to x), interferon beta-1a or (Betaseron or Extavia), or beta-1a or -1b product glatiramer acetate (Copardminister injections due to vsabri) for MS and have a sization, they are not requiramer acetate.	r kone) o	YES / NO
Exclusion Criteria:		oncurrent use of Avorsabri.	onex, Betaseron, E	ctavia, Rebif, Copaxone or		YES / NO
Age Restriction:						N/A
Prescriber Restrictions:	□ Pr	escribed by a neuro	logist or an MS sp	ecialist.		YES / NO
Coverage Duration:	□ Ap	pproval = 12 months	s, unless otherwise	specified.		YES / NO
*Approvals require	that all	bolded regions in t	he 'confirmation' c	olumn be documented in	member's c	hart notes.



GILFOTRIF

Affected Medications: GILOTRIF (Afatanib)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	indications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	_	factor receptor exon	ung cancer with known active 19 deletion or exon 21 (L858R)	YES / NO
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion Criteria:	Previous treatmen therapies	t of non-small cell lui	ng cancer with alternative	YES / NO
Age Restriction:	☐ Age >18 years			YES / NO
Prescriber Restrictions:	☐ Prescribed by an O	ncologist		YES / NO
Coverage Duration:	☐ Approval = 12 mor	nths, unless otherwise	e specified.	YES / NO
*Approvals require	that all bolded regions i	in the 'confirmation'	column be documented in men	ber's chart notes.



GLEEVEC

Affected Medications: GLEEVEC (imatinib)

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	•	epted indications not o started on Gleevec.	therwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	For indications o status of the leulNew patients wit authorization for	kemia must be reported th CML and ALL which is Gleevec.	adelphia chromosome (Ph) . Ph-positive may receive	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Gleevec.	tient must have Ph-pos ient must have Ph-posi	itive CML for approval of ive ALL for approval of	YES / NO
Exclusion Criteria:	unknown.	•	emia (CML) whose Ph status is eukemia (ALL) whose Ph status	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:		onths, unless otherwise	•	YES / NO
*Approvals require	that all bolded regions	s in the 'confirmation' of	olumn be documented in memb	er's chart notes.



GLUCAGON-LIKE PEPTIDE-1 AGONISTS

Affected Medications: BYETTA, BYDUREON

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical	☐ The patient is diagnosed as having type-2 diabetes with an HbA1c level	
Information:	greater than 7.	
information:	☐ The patient has a creatinine clearance of greater than 30mL/minute or normal kidney function.	
	☐ The patient demonstrated an inadequate treatment response, intolerance or contraindication to metformin AND a sulfonylurea OR a TZD.	YES / NO
	☐ If the patient has received previous Byetta therapy for at least 3	
	months, the patient demonstrated an expected reduction in HbA1c	
	since starting Byetta therapy.	
Appropriate		
Treatment		N/A
Regimen &		1.47.1
Other Criteria:		
Exclusion	☐ History of pancreatitis.	YES / NO
Criteria:		125 / 110
Age		N/A
Restriction:		11/71
Prescriber		N/A
Restrictions:		14/7
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



POLICY NAME: GONADOTROPIN

Affected Medications: CHORIONIC GONADOTROPIN, PREGNYL

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ Preoperative u	ed indications not otherw se in male infants/toddler th total epispadias and bla	s with hypospadias and	CONFIRMATION* YES / NO
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:	☐ Preoperative u	opic hypogonadism in mal se for hypospadias and ch ohy in male infants or tod	ordee OR total epispadias and	YES / NO
Exclusion Criteria:	or females, obe	, ,	gnosis or treatment) in males ent or habitual miscarriage, or r.	YES / NO
Age Restriction:	· ·	/ptorchidism, child or ado r epispadias, infant or tod		YES / NO
Prescriber Restrictions:				N/A
Coverage Duration:		months, unless noted other		YES / NO
l *Approvals require	that all bolded regio	ns in the 'confirmation' co	olumn be documented in memb	per's chart notes.



GRANIX

Affected Medications: GRANIX ® (tbo-filgrastim)

Effective Date: <u>07/01/2014</u>
Last Review Date: <u>12/11/2013</u>
Part D: No Part B: Yes (J1446)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required	Prophylaxis of febrile r	neutropenia (FN) or	other dose-limiting	
Medical	neutropenic events:			
Information:				
	receiving myelosup meets one of the form patient has ex with a previou patient is at his 20%) for deve patient's risk form patient is at look chemotherapy	opressive anti-cance of collowing: perienced FN or a dust cycle of chemothers of chemo	ose-limiting neutropenic event	
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion	☐ E. coli protein hype	ersensitivity.		
Criteria:		•	g or following chemotherapy o	YES / NO
Age	☐ 18 years and older			YES / NO
Restriction:				
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Approval = 6 mont	hs, unless otherwise	specified.	YES / NO
*Approvals require	that all bolded regions is	n the 'confirmation'	column be documented in mei	nber's chart notes.



POLICY NAME: GROWTH HORMONE

Affected Medications: GENOTROPIN®, HUMATROPE®, NORDITROPIN FLEXPRO®, NORDITROPIN NORDIFLEX®,

NUTROPIN AQ®, NUTROPIN®, OMNITROPE®, SAIZEN®

Covered Uses:		All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		Growth hormone (GH) deficiency (DF)	
		Non-GH deficient short stature (idiopathic short stature, ISS)	
	□ -	Turner's syndrome (TS)	VEC (NO
		SHOX (short stature homeobox-containing gene) deficiency	YES / NO
		Chronic renal insufficiency (CRI)	
		Prader-Willi syndrome (PW)	
		Short child born small for gestational age (SGA) or with intrauterine	
		growth retardation (IUGR) including those with Silver-Russell syndrome	
		Noonan syndrome (NS)	
		Short bowel syndrome (SBS)	
		Human Immunodeficiency Virus (HIV) infection with wasting or	
	(cachexia	
		HIV-associated failure to thrive	
Required	Child	d/adolesc GH DF initial tx,	
Medical		eval by pediatric endocrinologist (PE),	
Information:		documented GH stim test (levodopa, insulin-induced hypoglycemia,	
	6	arginine, clonidine, glucagon) w/GH response < 10 ng/mL AND	
		baseline height (Ht) less than the 3rd percentile (pct) for gender/age	
		AND	
		pretx Ht growth rate (GR) child < 3 yrs of < 7 cm/yr and child ≥ 3 yrs of	
		< 4 cm/yr OR	
		child any age GR less than the 10th pct for age/gender based on min 6	
	ı	months of data.	
		Child w/brain radiation does not have to meet baseline Ht crit.	YES / NO
		Congenital hypopituitarism does not have to meet Ht or GR crit.	
		Child w/hypophysectomy, approve.	
		d/adolesc GH DF cont tx,	
		GR increased by 2.5 cm/yr or more in most recent yr (MRY) per MD	
		AND epiphyses open (older than 12 yrs), both crit exclude adolesc	
		w/hypopituitarism.	
		Review GR annually (not applied to hypopituitarism).	
		Adoles/young adult w/completed linear growth (GR less than 2 cm/yr),	
	l	review for adult GH DF.	



	□ > 18 yrs, auth not allowed if midparental ht attained.
	ISS child w/open epiphyses,
	☐ 6 mo trial if baseline Ht < 3rd pct (greater than 2 SD below mean for
	gender/age) AND
	□ pretx GR child < 3 yrs of < 7 cm/yr and child ≥ 3 yrs of < 4 cm/yr OR
	child any age GR < the 10th pct for age/gender based on min 6 months
	of data AND
	☐ PE certifies child's basic activities of daily living limited by SS and has
	condition which GH is/may be effective AND
	☐ PE certifies via bone-age x-ray, predicted adult Ht less than 3rd pct.
	☐ Auth after initial tx (auth for 12 mos) based on adequate clinical
	response (annualized GR doubles).
	☐ Cont tx (after 12 to 18 mos), GR increased by 2.5 cm/yr or more in MRY
	per MD AND epiphyses open (older than 12 yrs).
	□ > 18 yrs, auth not allowed if midparental ht attained.
	☐ Adult GH DF or PW/trans adoles, eval by or in consultation
	w/endocrinologist (start and annually).
	□ NS/SGA/SHOW/child PW, eval by PE.CRI, eval by PE or nephrologist.
Appropriate	Adult GH DF (start)
Treatment	□ document diagnosis of GH DF due to adult-onset (GH alone or multiple
Regimen &	hormone deficiencies/hypopituitarism from pituitary dz, hypothalamic
Other Criteria:	dz, surgery, cranial radiation tx, tumor txment, traumatic brain injury,
	or subarachnoid hemorrhage) or due to childhood-onset (GH not rec in
	adults who had GH tx as child for uses not due to GH DF) AND
	□ negative response to 1 GH stim test (insulin tolerance [peak less than 5
	mcg/L], or glucagon [peak less than 3 mcg/L]) [GHRH plus arginine may
	be used if available] (exclude stim test for childhood-onset due to
	mutations, lesions, congenital defects), transition adoles off
	somatropin 1 mo before retesting OR
	□ 3 or more pituitary hormone deficiencies (TSH, ACTH, LH/FSH, or AVP) YES / NO
	AND serum IGF-1 84 microg/L or less using the Esoterix ECB RIA or
	age/gender adjusted serum IGF-1 SDS below the 2.5 percentile.
	TS start
	□ female
	□ short stature (SS)
	SHOX start
	□ open epiphyses.
	CRI w/growth failure (GF) start, approve.
	Child PW w/GF or adult PW, approve.
	NS start,
	□ baseline ht less than 3rd percentile.



	TS/SHOX/CRI/child PW/NS, cont tx,	
	☐ GR increased by 2.5 cm/yr or more in most recent yr (MRY) AND	
	□ epiphyses open	
	SGA/IUGR start	
	□ born SGA AND	
	□ no sufficient catch-up growth before age 4 yr, and age 2 to 8 yrs,	
	☐ if older than 8 yrs, approve 1 yr trial if prepubertal, AND	
	□ baseline ht less than 3rd percentile for gender/age	
	☐ Cont tx: GR increased by 2.5 cm/yr or more in most recent, if aged	
	2 to 8 yrs, or by 3 or more cm/yr if older than 8 yrs and	
	prepubertal.	
	HIV w/wasting or cachexia,	
	☐ HIV-positive AND have 1 of the following,	
	☐ documented unintentional wt loss ≥ 10% from baseline OR	
	□ wt < 90% of the lower limit of ideal body wt OR	
	□ BMI ≤ 20 kg/m2 AND	
	□ able to consume or be fed via parenteral or enteral feedings 75%	
	or more of maintenance energy requirements based on current	
	body weight AND on antiretroviral tx ≥ 30 days prior to beginning	
	GH tx and will continue antiretroviral tx throughout GH txment.	
	☐ Repeat 12 or 24-wk courses of GH may be authorized after initial	
	12 or 24-wk GH course provided that they are off GH for at least 1	
	mo and meet all of previous HIV criteria.	
	HIV-assoc failure to thrive	
	☐ Able to consume or be fed via parenteral or enteral feedings 75%	
	or more of maintenance energy requirements based on current	
	body wt AND on antiretroviral tx ≥ 30 days prior to beginning GH	
	tx and will continue antiretroviral tx.	
	SBS	
	□ receiving specialized nutritional support.	
	□ pts eval on case-by-case basis for more than one 4-wk course per	
	yr.	
Exclusion	☐ Use in the management of acute critical illness due to complications of	
Criteria:	surgery, trauma, or with acute respiratory failure, as antiaging therapy,	
	to improve functional status in elderly, somatopause, enhancement of	
	athletic ability, bone marrow transplant (BMT) without total body	
	irradiation, bony dysplasias, burn injury, cardiac transplantation,	/ NO
	central precocius puberty, chronic fatigue syndrome, congenital	
	adrenal hyperplasia, constitutional delay of growth and puberty,	
	corticosteroid-induced short stature including a variety of chronic	
	glucocorticoid-dependent conditions, such as asthma, juvenile	



	rheumatoid arthritis, after renal, heart, liver, or BMT, Crohn's disease,	
	cystic fibrosis, dilated cardiomyopathy/heart failure, end-stage renal	
	disease in adults undergoing hemodialysis, Down's syndrome, familial	
	dysautonomia, fibromyalgia, HIV-infected patients with alterations in	
	body fat distribution, infertility, kidney transplant patients (children)	
	with a functional renal allograft, liver transplantation, multiple system	
	atrophy, myelomeningocele, obesity, osteogenesis imperfecta,	
	osteoporosis (postmenopausal, idiopathic in men, glucocorticoid-	
	induced), thalassemia, and X-linked hypophosphatemic rickets (familial	
	hypophosphatemia, hypophosphatemic rickets).	
Age	☐ TS, children.	
Restriction:	□ SHOX/CRI/NS, children/adolescents.	WEG / NO
	□ SGA, 2 to 8 yrs.	YES / NO
	☐ HIV failure to thrive, < 17 yrs.	
	☐ SBS/HIV cachexia/wasting, adults	
Prescriber	☐ For adults, the endocrinologist must certify that the somatropin is not	YES / NO
Restrictions:	being prescribed for anti-aging therapy or to enhance athletic ability.	
Coverage	☐ GH DF = 12 months	
Duration:	□ SBS = 4 weeks/yr	VEC / NC
	□ Non-GH DF ISS = 6 months	YES / NO
	☐ HIV wast/cach = 24 weeks	
	☐ HIV failure to thrive = 12 weeks	
*Approvals require	hat all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



HETLIOZ

Affected Medications: HETLIOZ (tasimelteon)

Effective Date: 09/01/2014
Last Review Date: 07/09/2014
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION* YES / NO
Required Medical	 □ Documentation of being legally blind □ Documentation of 30 day sleep log or actigraphy 	YES / NO
Information:	☐ Circadian biochemical analysis (collected over several weeks)	
Appropriate Treatment Regimen & Other Criteria:	 □ If applicable: Beta-blocker must be discontinued unless clinically inappropriate, then documentation as to clinical need of continuation of Beta-blocker and acknowledgment of likely diminished efficacy. □ Polysomnogram with documentation of treatment or having ruled out other sleep disorders. 	YES / NO
Exclusion Criteria:		N/A
Age Restriction:		N/A
Prescriber Restrictions:	☐ Neurologist, Internist board certified in Sleep Medicine, Sleep Specialist	YES / NO
Coverage Duration:	☐ Approval = 6 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in members	er's chart notes.



HIGH RISK MEDICATIONS

Affected Medications: CLOMIPRAMINE HCL, DOXEPIN HCL, GUANFACINE HCL, IMIPRAMINE HCL, IMIPRAMINE PAMOATE, METHYLDOPA TAB, METHYLDOPATE HCL INJ, RESERPINE TAB, THIOIDAINE HCL TAB, TRIMIPRAMINE

MALEATE CAP

Effective Date: <u>01/01/2014</u> Last Review Date: <u>06/12/2013</u>

Member:	DOB: II	D#: P	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved indication	is not otherwise excl	luded from Part D.	CONFIRMATION* YES / NO
Required				
Medical				N/A
Information:				
Appropriate Treatment	 Recent documentation (pas therapy in patients over the 	-	enefit of continuation of	
Regimen & Other Criteria:	☐ Documentation that formul high risk would not be medi	ary alternatives that		YES / NO
Exclusion Criteria:				YES / NO
Age Restriction:	☐ Policy only applies to those	over the age of 65		N/A
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Approval = 12 months, unle	ss otherwise specifie	ed.	YES / NO
*Approvals require	that all bolded regions in the 'co	nfirmation' column l	be documented in memb	er's chart notes.



HIZENTRA

Affected Medications: HIZENTRA (immune globulin)

Effective Date: 01/01/2014INT Last Review Date: 9/23/2012 Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:		N/A
Appropriate Treatment Regimen & Other Criteria:	 Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. If administered outside of a controlled healthcare setting, appropriate treatment (eg, anaphylaxis kit) will be made available for managing an acute hypersensitivity reaction to immune globulin. 	YES / NO
Exclusion Criteria:	☐ IgA deficiency with antibodies to IgA and a history of hypersensitivity, history of anaphylaxis or severe systemic reaction to the administration of human immune globulin or product components, and hyperprolinemia.	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



HUMIRA

Affected Medications: HUMIRA (adalimumab)

Effective Date: 01/01/2014 Last Review Date: 9/23/2012 Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	□ Patients already started on adalimumab for covered uses.	YES / NO
Required	☐ FDA approved indication must be documented in the member's chart	
Medical	notes within the most recent 6 months.	
Information:	☐ Documentation of complete and current treatment course required.	
	☐ For treatment of RA: Laboratory test must confirm diagnosis of	
	Rheumatoid Arthritis: Anti-Cyclic Citrullinated Peptide Antibody(anti-	
	CCP) OR Rheumatoid Factor (RF).	
	☐ Negative Latent TB screening with either by TB skin test or an	YES / NO
	interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) prior to request. OR	ILS / NO
	☐ For positive latent TB, patient must have completed or receiving treatment for LTBI.	
	☐ For those at risk for Hepatitis B (HBV) infection, HBV has been ruled out	
	or treatment has been initiated.	
Appropriate	Rheumatoid arthritis (RA) & Juvenile idiopathic arthritis (JIA)	
Treatment	☐ Patient has failed at least 12 weeks of therapy of at least 2 DMARDs	
Regimen &	(hydroxychloroquine, leflunomide, methotrexate, minocycline,	
Other Criteria:	sulfasalazine) OR	
	☐ Patient has failed at least 12 weeks of therapy of another biologic	
	agent [abatacept (Orencia), rituximab(Rituxin), tocilizumab(Actemra),	
	adalimumab (Humira), entanercept(Enbrel), infliximab(Remicade),	
	certolizumab(Cimzia), golimumab(Simponi)].	
	Psoriatic Arthritis (PsA)	VEC / NO
	□ pt tried ≥ 1 oral DMARD for ≥ 12wks (hydroxychloroquine, leflunomide,	YES / NO
	sulfasalazine, minocycline, methotrexate).	
	Plaque psoriasis (PP)	
	□ pt has tried at least one systemic therapy (methotrexate, cyclosporine,	
	isotretinoin) OR phototherapy (UVB, PUVA).	
	Crohn's Disease (CD)	
	☐ Pt has tried ≥ 2 oral treatments for ≥ 12wks (corticosteroids,	
	azathioprine, cyclosporine, 6-mercaptopurine, MTX, tacrolimus, sulfasalazine, mesalamine or balsalazide)	
	Sanasarazine, mesaranine or saisaraziae)	



Exclusion Criteria:	 Concurrent use of: abatacept (Orencia), rituximab(Rituxin), tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel), infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi). Use in the management of osteoarthritis, ulcerative colitis, recurrent spontaneous pregnancy loss, in vitro fertiliation (IVF). Intra-articular injection of adalimumab. Positive test for tuberculosis, active HZV, HCV or HBV. 	YES / NO
Age Restriction:	□ RA, PsA, PP, AS: Adults.	YES / NO
Prescriber Restrictions:	 □ CD: prescribed by or in consultation with a GI specialist. □ PP: in consultation with a dermatologist. 	YES / NO
Coverage Duration:	☐ Approval =12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



ILARIS

Affected Medications: ILARIS (canakinumab)

Effective Date: 04/22/2012
Last Review Date: 02/08/2012
Part D: No Part B: Yes

Covered Uses:	 All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on canakinumab (Ilaris). 	YES / NO
Required Medical Information:		N/A
Appropriate	☐ Initial approval for MWS or FCAS, authorize one dose.	
Treatment	☐ After up to 8 weeks of therapy if the patient has had a response to	WEG / NO
Regimen &	therapy as determined by prescribing physician an additional 12	YES / NO
Other Criteria:	months authorization is allowed.	
Exclusion Criteria:	 Treatment of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA). Treatment of systemic juvenile idiopathic arthritis (JIA). Treatment of gout.Treatment of rheumatoid arthritis. Treatment of chronic obstructive pulmonary disease (COPD). Treatment of type 2 diabetes mellitus. When used in combination with tumor necrosis factor (TNF) blocking agents (e.g., etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept. Coverage is not recommended for circumstances not listed under Covered Uses. 	YES / NO
Age Restriction:		YES / NO
Prescriber		N/A
Restrictions:		14//
Coverage	☐ MWS or FCAS: Initial approval = one dose.	
Duration:	☐ Subsequent approval= 12 months, with pt response. that all bolded regions in the 'confirmation' column be documented in members.	YES / NO



POLICY NAME: IMBRUVICA

Affected Medications: IMBRUVICA (ibrutinib)

Effective Date: 03/01/2014
Last Review Date: 12/11/2013
Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved	indications not othe	rwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ Recent serum cre	atinine		YES / NO
Appropriate Treatment Regimen & Other Criteria:	☐ FDA approved do:	sing as appropriate fo	or the clinical condition.	YES / NO
Exclusion Criteria:	☐ Use in combination	on with any other ant	i-neoplastic regimens.	YES / NO
Age Restriction:	☐ Age >18 years			YES / NO
Prescriber Restrictions:	□ Prescribed by an (Oncologist		YES / NO
Coverage Duration:		nths, unless otherwis	se specified. Se column be documented in me	YES / NO



INCIVEK

Affected Medications: INCIVEK (telaprevir)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: No

Member:	 DOB:	ID#:	Provider:		Dx:
Covered Uses:	All FDA-approved i	indications not othe	erwise excluded from Part	D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ Anti-HCV pos☐ Compensateserum albumencephalopa☐ Elevated ALT	tectable (please ind sitive d liver disease: (sen nin > 3.4, platelets athy or ascites)	dicate level): rum bilirubin < 1.5g/dL, IN = 75Kmm, no evidence of sy showing chronic HCV	R = 1.5,	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Incivek MUST be a and ribavirin Treatment therapy		bination with peginterfer	on alfa	YES / NO
Exclusion Criteria:	infection. Patients with recur transplantation. For use as monoth Patients who have protease inhibitor Patients who are p female partners ar	rrent hepatitis C afferapy. failed therapy with (e.g., Victrelis) for large pregnant or may be the pregnant.	n immune deficiency (HIV) eer liver (or other organ) n Incivek or another NS3/4	A nose	YES / NO
Age Restriction:	≥ 18 years of age				YES / NO
Prescriber Restrictions:	infectious disease	physician.	ion with a gastroenterolog	gist or	YES / NO
Coverage Duration:	 Initial Approval = 6 Total therapy = 12	weeks	CV RNA level .	in mamb	YES / NO



INCRELEX

Affected Medications: INCRELEX (mecasermin)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Diagnosis of severe primary insulin-like growth factor-1 (IGF-1) deficiency (Primary IGFD) or with growth hormone (GH) gene deletion with neutralizing antibodies to GH. □ Prior to starting therapy, a height ≥ 3 SD below the mean for chronological age and sex, and an IGF-1 level ≥ 3 SD below the mean for chronological age and sex. □ One stimulation test showing patient has a normal or elevated GH level. □ For continuation of therapy, patient grew more than 2 cm/year. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:	 Epiphyseal closure, active malignancy, or concurrent use with GH therapy. Patient has secondary causes of IGF-1 deficiency (e.g., hypothyroidism, malignancy, chronic systemic disease, skeletal disorders, malnutrition, celiac disease). 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	□ Endocrinologist	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified. that all bolded regions in the 'confirmation' column be documented in member	YES / NO



INFERGEN

Affected Medications: INFERGEN (Interferon Alfacon-1)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION*
		YES / NO
Required	☐ Diagnosis of chronic hepatitis C and meets the following criteria:	
Medical	☐ Detectable viral load prior to starting therapy,	
Information:	☐ Patient had a documented adverse reaction (ADR) or is at higher	
	risk for an ADR to a pegylated interferon.	YES / NO
	☐ If used as monotherapy, must have a contraindication or intolerance to	
	ribavirin.	
	TIDOVIII.	
Appropriate		
Treatment		NI/A
Regimen &		N/A
Other Criteria:		
Exclusion	☐ Decompensated liver disease, autoimmune hepatitis, uncontrolled	VEC / NO
Criteria:	major depression or severe mental illness.	YES / NO
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = up to 48 weeks	YES / NO
Duration:		
*Approvals require	that all holded regions in the 'confirmation' column be documented in members	er's chart notes.



INLYTA

Affected Medications: INLYTA® (axitinib)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required		
Medical		N/A
Information:		NA
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion		NI/A
Criteria:		N/A
Age		NI/A
Restriction:		N/A
Prescriber		NI/A
Restrictions:		N/A
Coverage	☐ Approval =12 months, unless otherwise specified.	YES / NO
Duration:		·
*Approvals require	that all bolded regions in the 'confirmation' column be documented in men	nber's chart notes.



POLICY NAME: INVEGA SUSTENNA

Affected Medications: INVEGA SUSTENNA (Paliperidone Palmitate Extended-Release Injectable Suspension)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required Medical Information:	 □ Diagnosis of acute and maintenance treatment of schizophrenia. AND □ The patient has a history of non-compliance and/or refuses to utilize oral medication. AND □ The patient has received at least ONE of the following: □ three test doses of oral Risperdal (risperidone) □ three test doses of oral Invega □ previous use of Invega Sustenna. □ If the patient is increasing the dose of Invega Sustenna, the patient must have a history of two prior injections of Invega Sustenna. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:	□ Diagnosis of dementia-related psychosis.□ Prior use of risperidone demonstrated a hypersensitivity reaction.	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	☐ Psychiatrist or receiving input from a psychiatry practice	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all holded regions in the 'confirmation' column be documented in memb	er's chart notes



IVIG

Affected Medications: BIVIGAM, CARIMUNE-NF, GAMMAGARD LIQUID, GAMMAGARD S/D, GAMMAPLEX,

GAMUNEX-C

Effective Date: 01/01/2014 Last Review Date: 09/23/2012 Part D: Yes Part B: Yes

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:		All FDA-approved in	dications not other	wise excluded from Part D.	CONFIRMATION*
Coron and Coron		Guillain-Barre Syndi		Mise exercises from tare 5.	
		Myasthenia Gravis.			
		•	flammatory Demyle	ninating Polyneuorapthy (CIDP)	YES / NO
				athy(MMN), Multifocal Acquired	
		•	·	opathy (MADSAM), pure	
		sensory CIDP).	,	, , , , , , , , , , , , , , , , , , , ,	
		Dermatomyositis.			
		Lambert - Eaton My	asthenic Syndrome		
		Relapsing-Remitting	-		
		Symptomatic HIV.			
		Immune Thrombocy	ytopenic Purpura (Id	diopathic, Acute, Chronic).	
		Chronic Lymphocyti	ic Leukemia w/ asso	ciated	
		hypogammaglobuli	nemia.		
		Bone Marrow/Sten	n Cell transplantation	n.	
		Kawasaki Disease.			
		Transplantation reje	ection (kidney, stem	n-cell, antibody-mediated).	
		Autoimmune Muco	cutaneous Blisterin	g Diseases (MBD) (Pephigus	
		Vulgaris, Pemphigus	s Foliaceus, Bullous	Pemphigoid, Cicatrical	
		Pemphigoid, Benigr	n mucous membran	e Pemphigoid, Epidermolysis	
		Bullosa Acquisita).			
Required		All indications:			
Medical		serum immunoglo	bulin concentration	ns AND	
Information:		patient weight			YES / NO
		ITP: current platele	t count		TES / NO
		HIV: entry CD4+ cou			
		CIDP, MADSAM, MI	MN, Sensory CIDP: r	nerve conduction tests	
Appropriate				e made per CMS guidance to	
Treatment		-		iagnosis of PID AND	
Regimen & Other Criteria:		administered in the	•		
Other Criteria:	PI	O or Primary Humora			
		Hypogammaglobuli		Unspecified)	
		Immunodeficiency	with Increased IGM		



YES / NO
YES / NO



	□ presence of repeated bacterial infections	
	Bone Marrow/Stem Cell Transplantation:	
	☐ Cytomegalovirus (CMV) seropositive before transplantation OR	
	☐ CMV seronegative AND	
	□ seropositive marrow donors AND	
	□ patient undergoing allogenic transplantation for hematologic	
	neoplasms.	
	Guillain-Barre/Myashtenia Gravis/RRMS:	
	□ only after failure or contraindication to at least one other therapy	
	and/or rapidly progressive form of the disease.	
	CIDP and variants:	
	☐ after a measurable response to a therapeutic trial of prednisone AND	
	for long-term treatment periodic dose reductions/withdrawals must be	
	conducted to validate continued use.	
	Mucocutaneous Blistering Diseaseases:	
	$\hfill \square$ after at least one conventional therapy (unless conventional therapy	
	contraindicated) OR in rapidly progressive disease in combination with	
	conventional therapy when conventional therapy would be insufficient.	
Exclusion	☐ IgA deficiency.	YES / NO
Criteria:		,
Age	☐ HIV: less than or equal to 13 years.	YES / NO
Restriction:	□ Bone Marrow/Stem Cell Transplantation: ≥ 20 years.	
Prescriber	☐ Primary immunodeficiency (PID), if prescribed by a or in consultation	
Restrictions:	with an immunologist.	YES / NO
	☐ CIDP, CIDP Variants, MMN: consultation with neurologist or	
	rheumatologist.	
Coverage	☐ MBD: Approval = 3 months (short-term treatment only).	YES / NO
Duration:	☐ Other uses: Approval = 12 months, unless otherwise specified.	123 / 110
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



JAKAFI

Affected Medications: Jakafi (Ruxolitinib)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
covered oses.	All FDA-approved indications not otherwise excluded from Part D.	
		YES / NO
Required	☐ Have intermediate or high-risk myelofibrosis.	
Medical		YES / NO
Information:		
Appropriate		
Treatment		NI/A
Regimen &		N/A
Other Criteria:		
Exclusion		N/A
Criteria:		IV/A
Age		N/A
Restriction:		IV/A
Prescriber		N/A
Restrictions:		IV/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



KADCYLA

Affected Medications Kadcyla (Ado-trastuzumab))

Effective Date: 06/01/2014
Last Review Date: 05/10/2013
Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ Applies to new starts only.	YES / NO
Required	☐ Diagnosis of HER2-positive metastatic breast cancer.	
Medical	☐ Previously received trastuzumab and a taxane, separately or in	YES / NO
Information:	combination.	
Appropriate	☐ Received prior therapy for metastatic disease OR developed disease	
Treatment	recurrence during or within six months of completing adjuvant	YES / NO
Regimen &	therapy.	
Other Criteria:		
Exclusion	☐ Patient has symptomatic CHF or left ventricular dysfunction as defined	
Criteria:	as LVEF < 40%.	YES / NO
	☐ Concurrent diagnosis of interstitial lung disease, pneumonitis, or	ils / No
	known active hepatitis B or hepatitis C.	
	☐ Platelet count <100,000/mm3 prior to initiation of treatment.	
Age	☐ Age greater than 18	YES / NO
Restriction:		
Prescriber	☐ Prescribed by or after consultation with an oncologist.	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



POLICY NAME: KYNAMRO

Affected Medications: KYNAMRO (Mipomersen Sodium)

Effective Date: 10/01/2013
Last Review Date: 08/14/2013
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ Applies to new starts only.	YES / NO
Did		
Required	☐ Diagnosis of homozygous familial hypercholesterolemia.	
Medical	☐ Concomitant usage of multiple lipid-lowering treatments (at least 3):	
Information:	statins, ezetimibe, nicotinic acid, bile acid sequestrant, fibrates	
	☐ Concomitant usage of LDL apheresis (or documented failure or	WEG / NO
	justification for avoidance)	YES / NO
	Recent Lipid Panel (within 3 months)	
	☐ Liver Function Test (within 3 months)	
	□ Documentation of completion of Kynamro REMS program	
	☐ Documentation of risk of hepatotoxicity with patient	
Appropriate	☐ Documented plan to monitor LFT's every 3 months.	
Treatment		YES / NO
Regimen &		
Other Criteria:		
Exclusion	☐ Moderate or severe hepatic impairment (Child-Pugh class B or C)	
Criteria:	☐ Active Liver Disease or unexplained persistent elevations of serum	YES / NO
	transaminases	
	☐ Severe renal impairment	
Age	□ Age > 18	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in mem	ber's chart notes.



KINERET

Affected Medications: KINERET (Anakinra)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	 □ Juvenile idiopathic polyarticular course □ Systemic onset JIA □ Ankylosing spondyl □ Still's disease (SD). □ Neonatal Onset Mu 	arthritis (JIA) or juve e (regardless of type itis. ultisystem Inflamma	wise excluded by benefit desigenile rheumatoid arthritis (JRA) of onset) tory disease (NOMID) as and articular (CINCA)	
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:	etanercept, or inflix of these therapies JIA/JRA (regardless of o	kimab for at least 2 ronset) Tried or intolerant to acept for at least 2 m	colizumab pegol, golimumab, months or was intolerant to on etanercept, adalimumab, nonths or was intolerant to one	YES / NO
Exclusion Criteria:	or type 2 diabetes r Anakinra should no (etanercept, adalim golimumab), or aba	mellitus. It be given in combir numab, infliximab, co ntacept, rituximab, o		
Age Restriction:	☐ Rheumatoid arthrit	is (RA) and Still's dis	ease = adults.	YES / NO
Prescriber Restrictions:				N/A



Coverage	☐ All other conditions/uses, approval = 12 months.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



KUVAN

Affected Medications: KUVAN (sapropterin)

Effective Date: 10/01/2009 Last Review Date: 08/12/2009 Part D: No Part B: Yes

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:		All FDA approved i Hyperphenylalanin		wise excluded by benefit design.	CONFIRMATION* YES / NO
Required Medical Information:		Current Phe conce ☐ Age ≤ 12 y ☐ Age ≥ 12 y	ntration must be cor ears: Phe level <u>must</u>	treatment course required. sistent with the following: be > 6mg/dL (360 μM) be > 10mg/dL (600 μM) at least monthly	YES / NO
Appropriate Treatment Regimen & Other Criteria:		rationale for avoid Phe restrict If patient has failed treatment with Kurthe following: Phe restrict treatment Initial dose If I moon moon moon moon moon moon moon mo	ance to the following ted diet as monothed monotherapy with van is warranted, treeted diet must be machined and and emust be 10mg/kg/dolood Phe does not conth, dose can be inconth	rapy Phe restricted diet and atment must be consistent with intained during Kuvan lay x 1 month lecrease from baseline after 1 creased to 20mg/kg/day x 1 entation of treatment success. discontinued in patients whose	YES / NO
Exclusion Criteria:		Prior intolerance o Doses greater than	_	requested medication	YES / NO
Age Restriction:					N/A
Prescriber Restrictions:					N/A
Coverage Duration:		Initial approval = 2 Subsequent appro	val = 6 months		YES / NO
*Approvals require	tha	t all bolded regions i	in the 'confirmation'	column be documented in memb	per's chart notes.



POLICY NAME: KYNAMRO

Affected Medications: KYNAMRO (Mipomersen Sodium)

Effective Date: 03/01/2014
Last Review Date: 08/14/2013
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ Applies to new starts only.	YES / NO
Required	☐ Diagnosis of homozygous familial hypercholesterolemia.	
Medical	☐ Concomitant usage of multiple lipid-lowering treatments (at least 3):	
Information:	statins, ezetimibe, nicotinic acid, bile acid sequestrant, fibrates	
Tillorillation:	☐ Concomitant usage of LDL apheresis (or documented failure or	
	justification for avoidance)	YES / NO
	☐ Recent Lipid Panel (within 3 months)	ILS / NO
	☐ Liver Function Test (within 3 months)	
	□ Documentation of completion of Kynamro REMS program	
	□ Documentation of risk of hepatotoxicity with patient	
	2 Secumentation of the patients, with patient	
Appropriate	☐ Documented plan to monitor LFT's every 3 months.	
Treatment		YES / NO
Regimen &		
Other Criteria:		
Exclusion	☐ Moderate or severe hepatic impairment (Child-Pugh class B or C)	
Criteria:	☐ Active Liver Disease or unexplained persistent elevations of serum	YES / NO
	transaminases	
	☐ Severe renal impairment	
Age	□ Age > 18	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



LETAIRIS

Affected Medications: LETAIRIS (ambrisentan)

Effective Date: 01/01/2014 Last Review Date: 09/23/2012

Member:	DOB: ID#: Provider:	_ Dx:
Covered Uses:	 □ All FDA-approved indications not otherwise excluded from Part D. □ Patients currently on Letairis or Tracleer for treatment of pulmonary arterial hypertension. 	CONFIRMATION* YES / NO
Required Medical Information:	 □ Documentation to support NYHA Classification of II, III or IV. □ Liver Function Tests within normal limits prior to initiation. □ Documentation of Acute Vasoreactivity Testing. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 □ Supportive care should be considered as first-line (anticoagulants, diuretics, oxygen, digoxin) - not required. □ Documentation of trial with at least 1 PDE5 inhibitor (unless contraindicated) OR patient at high risk necessitating endothelin receptor antagonist. □ Patients currently on Letairis or Tracleer may continue therapy if they have a diagnosis of PAH. 	YES / NO
Exclusion Criteria:	 Pregnancy. PAH secondary to heart failure w/ severe systolic dysfunction. Evidence of liver dysfunction. Tracleer: concomitant administration of glyburide, cyclosporine, droneadarone, everolimus, nilotinib. 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	☐ Prescribed by or in consultation with a cardiologist or a pulmonologist.	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO



LEUKINE

Affected Medications: LEUKINE (sargramostim)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	□ treatment of chemotherapy-induced febrile neutropenia (FN),	
	□ myelodysplastic syndromes (MDS),	YES / NO
	□ acute lymphocytic leukemia (ALL)	
Required	☐ Complete blood counts with differential and platelet counts will be	
Medical	monitored at baseline and regularly throughout therapy.	
Information:	Treatment of acute FN:	
	☐ 1) patient has a non-myeloid cancer and is currently receiving	
	treatment with myelosuppressive anti-cancer drugs, AND	
	☐ 2) meets one of the following:	
	☐ a) patient received prophylactic filgrastim or sargramostim during	
	the current chemotherapy cycle, OR	
	□ b) patient is at risk for infection-associated complications or poor	
	clinical outcomes of FN.	YES / NO
	AML and ALL:	, ,
	☐ Leukine will be used following induction or consolidation	
	chemotherapy.	
	MDS:	
	☐ patient has neutropenia and recurrent or resistant infections.	
	☐ Leukine is used for one of the following reasons:	
	1) mobilization of peripheral blood progenitor cells (PBPC),	
	2) use following PBPC transplant, or	
	3) use following bone marrow transplant.	
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion	☐ Hypersensitivity to yeast-derived products.	
Criteria:	☐ Use of Leukine within 24 hours preceding or following chemotherapy	
	or radiotherapy.	
	☐ Use of Leukine for prophylaxis of FN.	
	☐ When Leukine is used for treatment of acute FN: patient received	YES / NO
	prophylactic Neulasta during the current chemotherapy cycle.	
	☐ When Leukine is used for acute myelogenous leukemia (AML):	
	excessive leukemic myeloid blasts (≥ 10%) in the bone marrow or	
	peripheral blood.	



Age		N/A
Restriction:		
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 6 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: LEUPROLIDE

Affected Medications: ELIGARD, LEUPROLIDE INJ, LUPRON DEPOT, LUPRON DEPOT-PED

Effective Date: 01/01/2014 Last Review Date: 9/23/2012 Part D: Yes Part B: Yes

Member:	DOB: ID#: Provider:	Dx:
Covered Uses:	 □ All FDA-approved indications not otherwise excluded from Part D but specific to the following drugs as follows: . □ Prostate cancer (Lupron Depot OR Eligard) □ Endometriosis (Lupon Depot) □ Uterine leiomyomata (Lupon Depot) □ Treatment of central precocious puberty (Lupron Depot Ped) □ Lupron Depot, Lupron Depot Ped: □ Ovarian cancer. □ Breast cancer. □ Preserve ovarian function/fertility in women undergoing chemotherapy. □ Induce amenorrhea during bone marrow transplant. □ Premenstral syndrome. □ Menstrual migraine. □ Catamenial pneumothorax. □ Paraphilias or other inappropriate sexual behaviors or disorders. □ Dysfunctional uterine bleeding . □ Lymphangioleiomyomatosis. 	CONFIRMATION* YES / NO
Required Medical Information:		N/A
Appropriate Treatment Regimen & Other Criteria:	 Premenstrual syndrome (PMS) for patients that have tried two other therapies (e.g., selective serotonin reuptake inhibitors [SSRIs], oral contraceptives [OCs]). Menstrual migraine approve if the patient has tried two other therapies for the treatment of acute migraine (e.g., NSAIDs, triptans, ergotamines) or prophylaxis of migraine (e.g., beta-blockers, amitriptyline, divalproex). 	YES / NO
Exclusion Criteria:	 Polycystic ovarian syndrome (PCOS). Hirsutism. Benign prostatic hyperplasia (BPH). Functional bowel syndrome/irritable bowel syndrome. Orchitis/epididmyo-orchitis. 	YES / NO



Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		N/A
Coverage	☐ Dysfunctional uterine bleeding, approval = up to 6 months	YES / NO
Duration:	☐ All other indications, approval = 12 months.	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: LIDODERM

Affected Medications: LIDODERM (LIDOCAINE) PATCH

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	□ All medically-accepte	ed indications not o	therwise excluded from Part D	. CONFIRMATION*
				YES / NO
Required				
Medical				N/A
Information:				
Appropriate	Post-Herpetic Neuralgia:			
Treatment	□ trial of gabapenti	in (unless contraind	licated).	
Regimen &		•	·	YES / NO
Other Criteria:				
Exclusion	☐ Rheumatoid arthritis			
Criteria:	☐ Fibromyalgia.			YES / NO
Age				N/A
Restriction:				IN/A
Prescriber				N/A
Restrictions:				IN/A
Coverage	☐ Approval = 12 month	ns, unless otherwise	specified.	YES / NO
Duration:				
*Approvals require	that all bolded regions in a	the 'confirmation'	column be documented in mer	nber's chart notes.



LUCENTIS

Affected Medications: LUCENTIS (ranibizumab)

Effective Date: 09/01/2011 Last Review Date: 07/13/2011 Part D: No Part D: Yes

Covered Uses:	☐ All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	Age Related Macular Degeneration Initial approval requires documented failure, intolerance, or clinical rationale for avoidance to the following: Intravitreal Avastin (bevacizumab) If an exception is warranted, please call 541-330-4999 or submit medical records documenting the justification.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	☐ Subsequent approval requires documentation of treatment success.	YES / NO
Exclusion Criteria:	Evidence of a current ocular or periocular infection	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	□ Ophthalmologist	N/A
Coverage Duration:	☐ Approval = 6 months	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in mem	ber's chart notes.



POLICY NAME: LUMIZYME

Affected Medications: LUMIZYME (alglucosidase alfa)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	☐ Diagnosis of Pompe disease was confirmed by an enzyme assay	
Medical	demonstrating a deficiency of GAA enzyme activity or by DNA testing	
Information:	that identifies mutations in the GAA gene.	YES / NO
	☐ Patient has late-onset (non-infantile) Pompe disease with no evidence of cardiac hypertrophy.	
Appropriate	☐ Appropriate medical support is readily available when Lumizyme is	
Treatment	administered in the event of anaphylaxis, severe allergic reaction, or	
Regimen &	acute cardiorespiratory failure.	YES / NO
Other Criteria:	,	
Exclusion		N/A
Criteria:		IN/ A
Age	□ ≥ 8 years of age	YES / NO
Restriction:		
Prescriber		NI/A
Restrictions:		N/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		·
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



MAKENA

Affected Medications: MAKENA (Hydroxyprogesterone Caproate) *Brand Only

Effective Date: <u>08/01/2011</u>
Last Review Date: <u>06/8/2011</u>
Part D: No Part B: Yes

Covered Uses:	All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Singleton pregnant patient □ history of singleton spontaneous preterm birth (<37 weeks) 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 □ Initial approval requires documented failure, intolerance, or clinical rationale for avoidance to one of the following: □ Generic 17 alpha hydroxyprogesterone □ Vaginal progesterone 	YES / NO
Exclusion Criteria:	 □ Current or history of any of the following: □ multiple gestations or other risk factors for preterm birth. □ Thrombosis or thromboembolic disorders □ Known or suspected breast cancer or other hormone-sensitive cancer, or history of these conditions □ Undiagnosed abnormal vaginal bleeding unrelated to pregnancy □ Cholestatic jaundice of pregnancy □ Liver tumors, benign or malignant, or active liver disease □ Uncontrolled hypertension. 	YES / NO
Age Restriction:	□ ≥ 16 years of age	YES / NO
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 20 weeks, unless otherwise specified.	YES / NO



MEKINIST

Affected Medications: MEKINIST (trametinib)

Effective Date: <u>09/01/2013</u> Last Review Date: <u>07/24/2013</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Unresectable or metastatic melanoma with BRAF V600E or V600K mutation detected by FDA approved test. No previous or concurrent use of BRAF inhibitor therapy (i.e. Zelboraf, Tafinlar). 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	☐ Assessment of Left-Ventricular Ejection Fraction (LVEF) will be completed before therapy and regularly during therapy per the package insert.	YES / NO
Exclusion Criteria:	☐ Use in combination with Tafinlar or Zelboraf	YES / NO
Age Restriction:	☐ Age > 18 years	YES / NO
Prescriber Restrictions:	☐ Oncologist or in consultation with an oncologist	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: MODAFINIL

Affected Medications: MODAFINIL

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved in	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required	Narcolepsy:			
Medical	□ confirmed by Sleep	Lab Evaluation.		
Information:	Obstructive Sleep Apn	ea (OSA):		
	□ confirmed by polys	omnography		
	☐ Documentation of s	status of CPAP utiliza	ition.	
	Shift Work Sleep Disor	der:		
	□ work the night shift	t (at least 6 hours be	tween the hours of 10pm and	YES / NO
	8am permanently of	or work the night shi	ft (at least 6 hours between the	,
	hours of 10pm and	8am) frequently (mo	ore than 5 times per month)	
	AND experience ex	cessive sleepiness w	hile working.	
	Mild obstructive sleep	apnea:		
	□ patient is using and	compliant with an o	oral appliance.	
Appropriate	Attention-deficit hyper	ractivity disorder (Al	OHD) and attention-deficit	
Treatment	disorder (ADD):			
Regimen &	□ patients must have	tried 2 alternative r	nedications for ADHD/ADD	
Other Criteria:	from 2 different cla	asses as follows:		
	□ methylphenid	ate products (e.g., m	ethylphenidate,	
	dexmethylphe	enidate),		YES / NO
	□ amphetamine	s (e.g., mixed amphe	tamine salts,	ILS / NO
	dextroamphet	amine),		
	□ atomoxetine,			
	□ bupropion or			
	□ tricyclic antide	epressants (TCAs e.g.	, imipramine, desipramine).	
Exclusion			ganic brain syndrome,	
Criteria:	☐ chronic fatigue syn			
		n primary insomnia,		
		in the treatment of	schizophrenia,	YES / NO
	□ seasonal affective of	•		
		vake disorders or sle		
	bipolar disorder (in	cluding bipolar depr	ession),	



	☐ fatigue and EDS in chronic traumatic brain injury,	
	☐ fatigue in post-polio patients, and	
	□ spasticity due to cerebral palsy.	
Age	□ ADHD or ADD, < 18 years	YES / NO
Restriction:	☐ For all other indications, Adults	
Prescriber		N/A
Restrictions:		N/A
Coverage	☐ Approval =12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



MOZOBIL

Affected Medications: MOZOBIL (plerixafor)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Mozobil will be used to mobilize hematopoietic stem cells for collection prior to autologous transplantation and used in combination with granulocyte-colony stimulating factor (ie, filgrastim or pegfilgrastim). Patient diagnosed with either non-Hodgkin's lymphoma or multiple myeloma. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:		N/A
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 6 months	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



POLICY NAME: NEULASTA

Affected Medications: NEULASTA (pegfilgrastim)

Member:	DOB:_	ID#:	Provider:	Dx:
Covered Uses:	prophylaxi other dose patients, r	is of chemotherapy-induce e-limiting neutropenic ever nobilization of peripheral b	erwise excluded from Part D , d febrile neutropenia (FN) or ats in intermediate and low risk blood progenitor cells (PBPCs).	CONFIRMATION* YES / NO
Medical Inform ation:	monitored For prophy 1) patient be receivin 2) meets of a) ev b) int ba OI C) ba AI AI co	If at baseline and regularly to ylaxis of FN or other doselhas a non-myeloid cancer and myelosuppressive anti-come of the following: patient has experienced FI rent with a previous cycle of patient is at high risk (greatermediate risk (10-20% risksed on chemotherapy regions and one chemotherapy regions and one chemotherapy regions and one chemotherapy is intended to patient is at significant in the consequences of FN. It is used for PBPC mobilizations and one chemotherapy is intended to the consequences of FN.	chroughout therapy. imiting neutropenic events: and is currently receiving or will ancer drugs, AND N or a dose-limiting neutropenic of chemotherapy, OR ater than 20% risk of FN) or k of FN) for developing FN men and patient's risk factors, where the receiving for the risk of FN for developing for the risk of FN for developing for the risk of FN for developing for the risk factors fed to be curative or adjuvant fisk for serious medical	YES / NO
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion Criteria:	☐ Use of New chemothe☐ Use of New	ulasta for treatment of che undergoing peripheral bloc	e or 24 hours after motherapy-induced FN.	YES / NO



	☐ Use in the management of myelodysplastic syndrome.	
Age Restriction:		N/A
Prescriber		NI/A
Restrictions:		N/A
Coverage	☐ Approval = 6 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require th	at all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: NEUPOGEN

Affected Medications: NEUPOGEN (filgrastim)

Member:	 DOB:	ID#:	Provider:	Dx:
Covered Uses:	worded more broad chemotherapy, patie chemotherapy, cand (BMT), patients undecollection and thera [SCN] (e.g., congenit neutropenia).	ly as cancer patients ents with acute mye er patients receiving ergoing peripheral by, and patients with all neutropenia, cycleted with human implication ficiency syndrome (dysplastic syndrome ulocytosis or neutro).	es (MDS).	CONFIRMATION* YES / NO
Required Medical Information:	monitored at baseling Prophylaxis of febril neutropenic events: 1) patient has a non be receiving myelos: 2) meets one of the appatient has event with a event with a event with a compatient is (10-20%) for and patient is chemotheral	ne and regularly thro le neutropenia (FN) i-myeloid cancer and uppressive anti-cand following: as experienced FN of a previous cycle of cl at high risk (greater developing FN base s risk factors, OR at low risk (< 10%) f py regimen and pat py is intended to be	or other dose-limiting d is currently receiving or will ter drugs, AND r a dose-limiting neutropenic	YES / NO



	☐ Treatment of acute FN:	
	1) patient has a non-myeloid cancer and is currently or will be receiving	
	myelosuppressive anti-cancer drugs AND	
	2) meets one of the following:	
	a) patient received prophylactic filgrastim or sargramostim	
	during the current chemotherapy cycle, OR	
	b) patient is at risk for infection-associated complications or	
	poor clinical outcomes of FN.	
	☐ Acute Myeloid Leukemia and Acute lymphocytic leukemia (ALL):	
	Neupogen will be used following induction or consolidation	
	chemotherapy.	
	☐ Leukemic Relapse: Neupogen will be used as an alternative or adjunct	
	to donor leukocyte infusions after allogeneic stem cell transplant.	
	☐ Myelodysplastic Syndromes (MDS):	
	☐ patient has neutropenia and recurrent or resistant infections,	
	OR	
	☐ patient has symptomatic anemia and Neupogen will be used in	
	combination with epoetin or darbepoetin.	
	☐ Neupogen is used for one of the following reasons:	
	1) mobilization of peripheral blood progenitor cells (PBPC),	
	2) use following PBPC transplant,	
	3) use following bone marrow transplant, or	
	4) severe chronic neutropenia.	
Appropriate		
Treatment Regimen &		N/A
Other Criteria:		
Exclusion	☐ E. coli protein hypersensitivity. Use of Neupogen within 24 hours	
Criteria:	preceding or following chemotherapy or radiotherapy.	
	☐ When Neupogen is used for treatment of acute FN: patient received	YES / NO
	prophylactic Neulasta during the current chemotherapy cycle.	
Λαρ		
Age Restriction:		N/A
Prescriber		N/A
Restrictions:		
Coverage	☐ Approval = 6 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



NEXAVAR

Affected Medications: NEXAVAR (sorafenib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	□ thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary),	
	☐ gastrointestinal stromal tumors (GIST),	YES / NO
	□ angiosarcoma.	
Required	☐ Renal Cell Carcinoma (RCC), patient has advanced RCC.	
Medical	☐ Hepatocellular Carcinoma (HCC), patient has unresectable HCC.	
Information:	☐ Follicular, papillary, or Hurthle cell thyroid carcinoma: patient has	
	clinically progressive or symptomatic metastatic disease with	
	nonradioiodine-responsive tumors at sites other than central nervous	
	system.	
	☐ Medullary thyroid carcinoma: patient has disseminated symptomatic	YES / NO
	disease with progression on vandetanib or vandetanib is not	
	appropriate.	
	☐ GIST: patient has progressive disease with an inadequate response to	
	imatinib or sunitinib.	
	☐ Angiosarcoma: Nexavar will be used as a single agent.	
Appropriate		
Treatment		N/A
Regimen &		,
Other Criteria: Exclusion		
Criteria:		N/A
Age		
Restriction:		N/A
Prescriber		N1 / A
Restrictions:		N/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



POLICY NAME: NITROFURANTOIN

Affected Medications: FURADANTIN, NITROFURANTOIN, MACROBID, MACRODANTIN

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved	d indications not other	wise excluded from Part D.	CONFIRMATION*
				YES / NO
Required	☐ Prescriber must a	acknowledge that med	cation benefits outweigh	
Medical	potential risks in	patients 65 years of ag	e or older.	
Information:	□ Documentation of	of CrCl of > 60 ml/min i	n the past 12 months.	YES / NO
	☐ This prior author	ization only applies to	quantities > 14 day supply.	
Appropriate	☐ Documentation of	of failure or rationale for	or avoidance of two other	
Treatment	antibiotics.			YES / NO
Regimen &	☐ Annual evaluatio	n of benefit for continu	uation of therapy.	TES / NO
Other Criteria:	☐ Annual evaluatio	n of respiratory status	to confirm no nitrofurantoin	
	related respirato	ry disease.		
Exclusion				N/A
Criteria:				N/A
Age	□ > age 65			N/A
Restriction:				IN/A
Prescriber				N/A
Restrictions:				IV/A
Coverage	☐ Approval = 12 mg	onths, or as otherwise	specified.	YES / NO
Duration:				
*Approvals require	that all holded regions	s in the 'confirmation'	column be documented in me	mber's chart notes.



NON-BENZODIAZEPINE SLEEP MEDICATIONS

Affected Medications: AMBIEN®, EDLUAR, LUNESTA®, ZALEPLON, ZOLPIDEM, ZOLPIMIST

Effective Date: <u>01/01/2014</u> Last Review Date: <u>05/22/2013</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	□ Diagnosis of insomnia	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 □ Patient has tried, failed and/or been intolerant to a 30-day trial of at least one of the following agents: Ramelteon (Rozerem), Doxepin (less than or equal to 6mg) (Silenor), or trazodone. □ Dosing for requested agents must be in accordance with FDA recommendations: □ Zolpidem: □ Female patient: max dose of: 5mg IR zolpidem or 6.25mg zolpidem ER or 1.75mg Intermezzo. □ Male patient: 5-10mg IR zolpidem or 6.25-12.5mg zolpidem ER or 3.5mg Intermezzo. □ Lunesta (eszopiclone): Age > 65 years: max dose 2mg □ Zaleplon: Age > 65 years: initial 5mg, max dose 10mg/day. 	N/A
Exclusion Criteria:		N/A
Age Restriction:	 □ This prior authorization only applies to patients > 65 years. □ > 18 years of age for approval. □ Ages 18 to 64, no authorization required. 	YES / NO
Prescriber Restrictions:		N/A
Coverage Duration:	□ Approval = 1 month	YES / NO



POLICY NAME: NUEDEXTA

Affected Medications: NUEDEXTA (dextromethorphan and quinidine)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:		All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required		Patient has amyotrophic lateral sclerosis (ALS) OR multiple sclerosis	
Medical		(MS).	YES / NO
Information:			TES / NO
Appropriate			
Treatment			N/A
Regimen &			IV/A
Other Criteria:			
Exclusion		Concomitantly taking other drugs containing quinidine, quinine,	
Criteria:		mefloquine, monoamine oxidase inhibitors (MAOIs), or drugs that both	
		prolong QT interval and are metabolized by CYP2D6.	
		Patient has a prolonged QT interval, congenital long QT syndrome or a	YES / NO
		history suggestive of torsades de pointes, or heart failure.	
		Patient has complete atrioventricular (AV) block without implanted	
		pacemaker or is at high risk of complete AV block.	
Age			N/A
Restriction:			IN/A
Prescriber			NI/A
Restrictions:			N/A
Coverage		Approval = 12 months, unless otherwise specified.	YES / NO
Duration:			
*Approvals require	that	all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



NUVIGIL

Affected Medications: NUVIGIL (armodafinil)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All medically-acce	oted indications not o	therwise exlcuded from Part D.	CONFIRMATION* YES / NO
Required	Narcolepsy			
Medical Information:	□ confirmed by S	Sleep Lab Evaluation.		
	Obstructive Sleep Apr	iea (OSA)		
	□ confirmed by poly	somnography		
	□ documentation is	provided of CPAP stat	us.	
	Shift Work Sleep Diso	rder		YES / NO
	□ work the night shi	ft (at least 6 hours be	tween the hours of 10pm and	,
	8am permanently	or work the night shif	t (at least 6 hours between the	
	hours of 10pm and	d 8am) frequently (≥5	times per month) AND	
	□ experience excess	ive sleepiness while w	orking.	
	Mild obstructive sleep	apnea		
	□ patient is using an	d compliant with an c	ral appliance.	
Appropriate	Attention-deficit hype	ractivity disorder (Al	OHD) and attention-deficit	
Treatment	disorder (ADD):			
Regimen & Other Criteria:		e tried two alternative t classes as follows:	e medications for ADHD/ADD	
	□ methylphenidate	products (e.g., methyl	phenidate,	
	dexmethylphenida		,	YES / NO
		· ·	ne salts, dextroamphetamine),	
	□ atomoxetine,	,	, , , , , , , , , , , , , , , , , , , ,	
	-	clic antidepressants (ΓCAs e.g., imipramine,	
	desipramine).	,,	· · · · ·	
Exclusion	☐ Use in the manage	ment of alcoholic org	anic brain syndrome, chronic	
Criteria:	fatigue syndrome,	EDS associated with	orimary insomnia, adjunctive	YES / NO
	therapy in the trea	tment of schizophrer	nia. seasonal affective disorder.	



	post-stroke sleep-wake disorders or sleep disorders, bipolar disorder	
	(including bipolar depression), fatigue and EDS in chronic traumatic	
	brain injury, fatigue in post-polio patients, and spasticity due to	
	cerebral palsy.	
Age	☐ ADHD or ADD in patients < 18 years.	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		IN/ A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		·
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: OCTREOTIDE

Affected Medications: OCTREOTIDE, SANDOSTATIN

Member:	DOB: ID#: Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	Acromegaly	
Medical	Initiation of therapy, patients meets the following:	
Information:	☐ Clinical evidence of acromegaly,	
	□ Pre-treatment high IGF-1 level for age/gender,	
	□ Patient has had an inadequate or partial response to surgery and/or radiotherapy OR	
	 there is a clinical reason for why the patient has not had surgery or radiotherapy (e.g., medically unstable conditions, patient is at high risk for complications of anesthesia because of airway difficulties, lack of an available skilled surgeon, patient refuses surgery or prefers the medical option over surgery, major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes). Continuation of therapy, the IGF-1 level decreased or normalized. 	
	Atypical lung carcinoids,	YES / NO
	use in combination with chemotherapy.	
	Islet cell tumors,	
	 patient has insulinoma, glucagonoma, or VIPoma. For MEN 1, patient meets one of the following: 1) Patient has insulinoma, glucagonoma, or VIPoma OR 2) Patient has pituitary adenoma and is symptomatic or has significant tumor burden. Primary CNS tumors, patient has recurrent meningiomas AND 	
	 □ unresectable tumors. Thymic carcinoma, □ patient has locally advanced, unresectable disease AND □ receiving octreotide injection post-radiation 	



Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion		NI/A
Criteria:		N/A
Age		N/A
Restriction:		IN/A
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		·
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



OLYSIO

Affected Medications: Olysio (Simeprevir sodium)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Documentation of genotype 1 chronic hepatitis C virus (HCV) Documentation of liver disease (including cirrhosis) with Child-Pugh Classification □ Documentation of Fibrosis Score □ Documentation if patient is Treatment-naïve, prior relapse, or prior partial responder □ Documentation of absence of Q80K variant 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Must be used in combination with peginterferon alfa and ribavirin. If peginterferon alfa or ribavirin is discontinued for any reason, simeprevir must also be discontinued. □ Documentation of contraindication to Interferon must then be used in combination with Sofosbuvir. Contraindication to Interferon is defined by one of the following conditions: □ Autoimmune hepatitis or other autoimmune disorder, □ hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic patients before treatment, □ major depression disorder with suicidal ideation – patient must have evaluation done by Psychologist within the 6 months of initiation of therapy, □ bipolar disorder, □ baseline neutrophil count <1,500/μL, □ baseline platelet count of < 90,000/μL, □ Preexisting cardiac disease (prior history of MI or stent placement) 	YES / NO
Exclusion Criteria:		N/A
Age Restriction:	□ 18 years of age or older	YES / NO
Prescriber	☐ Hepatologist, Gastroenterologist, Infectious Disease Specialist	YES / NO
Restrictions:		



POLICY NAME: OMONTYS

Affected Medications: OMONTYS (peginesatide)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION*
	worded as anemia associated with chronic kidney disease (CKD) in	
	adult patients on dialysis.	YES / NO
Required	☐ Hemoglobin (Hb) ≤ 10.0 g/dL prior to initiation of therapy	
Medical	☐ Hb ≤ 12.0 g/dl if previously on epoetin alfa or Aranesp	YES / NO
Information:	□ Documented dialysis patient	TES / NO
Appropriate Treatment Regimen & Other Criteria:	 Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition. Deny if Hb is more than 12.0 g/dl 	YES / NO
	☐ Patient has tried, failed, or is intolerant to Procrit or Aranesp	
Exclusion	☐ Any anemia due to causes other than CKD (e.g. folate deficiency, B-12	
Criteria:	deficiency, iron deficiency, hemolysis, bleeding, bone marrow fibrosis,	
	etc.)	
	☐ Use in CKD patients not recieving dialysis	
	☐ Use in patients receiving treatment for cancer and whose anemia is not due to CKD	YES / NO
	☐ Uncontrolled hypertension	
	☐ Use as a substitute for RBC transfusions in patients who require	
	immediate correction of anemia	
Age	□ Age ≥ 18 years	YES / NO
Restriction:		TES / NO
Prescriber Restrictions:	□ must be prescribed by a nephrologist	YES / NO
	The American Alexander of the American Street	\
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO



ONFI

Affected Medications: ONFI (clobazam)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required		
Medical		N/A
Information:		IN/A
Appropriate		
Treatment		
Regimen &		N/A
Other Criteria:		
Exclusion		N/A
Criteria:		IN/ A
Age		NI/A
Restriction:		N/A
Prescriber	☐ Neurologist or affiliated with a neurology practice	VEC / NO
Restrictions:		YES / NO
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		,
*Approvals require	that all bolded regions in the 'confirmation' column be documented in mer	mber's chart notes.



ORAL-INTRANASAL FENTANYL

Affected Medications: ABSTRAL, ACTIQ, FENTORA, FENTANYL CITRATE, LAZANDA, ONSOLIS

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved	indications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	of the cancer pain The patient is opic they have been ta of transdermal fer hydromorphone d	oid tolerant (Patients a king at least 60 mg of		VFS / NO
Appropriate Treatment Regimen & Other Criteria:	uncontrollable nau □ patient is unable t morphine sulfate, adverse events AN □ patient is on or wi patient is on intrav	o swallow, has dysphousea/vomiting OR o take 2 other short-a hydromorphone, etc) ID II be on a long-acting venous, subcutaneous	tients with cancer: agia, esophagitis, mucositis, or acting narcotics (eg, oxycodone, secondary to allergy or severe narcotic (eg, Duragesic), or the s, or spinal (intrathecal, e, hydromorphone, fentanyl	YES / NO
Exclusion Criteria:	who will not be ca adjustments made Use in the manag surgery/post-surge (acute abdominal	refully monitored and e if necessary. ement of acute and/c ery, trauma/post-trau pain, pelvic pain, mus esia (preoperative and	r postoperative pain including ma, acute medical illness	YES / NO
Age Restriction:	 Actiq, ≥ 16 years All other medication	ons, ≥ 18 years		YES / NO
Prescriber				N/A



Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ORENCIA

Affected Medications: ORENCIA (abatacept)

Member:		DOB:	ID#:	Provider:	Dx:	_
Covered Uses:		All FDA-approved indi	cations not other	wise excluded from Part D.	CONFIRMATION	*
		• •		arted on abatacept for a		
		covered use,	,	,	YES / NO	
		Felty's Syndrome,				
		Rheumatoid Arthritis	with visceral or sy	stemic symptoms		
		Juvenile Arthritis.				
Required		FDA approved indicati	on must be docui	nented in the member's ch	hart	
Medical		notes within the most	recent 6 months			
Information:		Documentation of con	nplete and currer	t treatment course require	ed.	
		For treatment of RA: L	aboratory test m	ust confirm diagnosis of		
		Rheumatoid Arthritis:	Anti-Cyclic Citrull	inated Peptide Antibody(ar	nti-	
		CCP) OR Rheumatoid I	Factor (RF).		N/A	
		Negative Latent TB scr	reening with eithe	er by TB skin test or an		
		interferon gamma rele	ease assay (e.g., C	FT-GIT, T-SPOT.TB) prior to	0	
		request. OR				
		For positive latent TB,	patient must hav	e completed or receiving		
		treatment for LTBI.				
Appropriate	Rh	eumatoid Arthritis (RA),			
Treatment		Patient has failed at le	ast 12 weeks of t	herapy of at least 2 DMARD	Ds	
Regimen &		(hydroxychloroquine,	leflunomide, met	hotrexate, minocycline,		
Other Criteria:		sulfasalazine) AND Pat	tient has failed at	least 12 weeks of therapy of	of	
		another biologic agent	t [abatacept (Ore	ncia), rituximab(Rituxin),		
		tocilizumab(Actemra),	adalimumab (Hu	mira), entanercept(Enbrel),		
		infliximab(Remicade),	certolizumab(Cir	nzia), golimumab(Simponi))]. YES / NO	
	Ju	venile idiopathic arthrit	is (JIA) [or Juveni	le Rheumatoid Arthritis (JF	RA)],	
		polyarticular course, a	pprove if the pati	ent has tried one of the		
		following biologic DM	ARDs, adalimuma	b, etanercept, or infliximab	b for	
		at least 2 months or w	as intolerant to o	ne of these therapies.		
Exclusion		Concurrent use of: aba	atacent (Orencia)	rituximah(Rituxin)		
Criteria:				mira), entanercept(Enbrel),	YES / NO	
				nina), entanercept(Enbrei), nzia), golimumah(Simponi)		



	☐ Use in the management of psoriasis, undifferentiated arthritis, or	
	systemic lupus erythematosus.	
Age	☐ Rheumatoid arthritis (RA), adults.	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Part B Approval =3 months for initial IV dose.	WEG / NO
Duration:	☐ Part D Approval =12 months, unless otherwise specified	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



PEGASYS

Affected Medications: PEGASYS® (peginterferon alfa-2a)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	indications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required	Hepatitis C:			
Medical	☐ HCV genotype			
Information:	☐ HCV RNA level			
	□ evidence of compe	ensated liver disease (serum bilirubin ≤ 1.5g/dL, INR	
	WNL, serum albun	nin ≥ 3.4, platelets WN	IL, absence of encephalopathy	
	or ascites)			
	□ evidence of active	liver disease (elevate	d LFTs, liver biopsy)	N/A
	□ evidence patient is	not currently using il	licit drugs or alcohol.	13,71
	Hepatitis B:			
	☐ HBeAg status (pos	itive/negative)		
	☐ HBV DNA level, AL	T level or liver biopsy	showing active liver disease	
	☐ HBV DNA level sho	ould be monitored eve	ry 3-6 mos during Tx.	
Appropriate	Hepatitis C:			
Treatment	☐ Patients must have	e detectable HCV RNA	levels	
Regimen &	□ evidence of compe	ensated liver disease		
Other Criteria:	□ evidence of active	liver disease		
	□ no evidence of cur	rent illicit drug or alco	hol abuse	
	□ Preferred treatme	ent is ribavirin and inte	erferon alfa combination	
	Hepatitis C:			
	☐ Genotype 1, initial	approval = 12 wks, su	bsequent approval is	
	additional 36wks (total = 48wks) IF HCV	RNA is reduced 2log10 AND	YES / NO
	undetectable (≤ 50	OIU/mL) OR subseque	nt approval is additional 12wks	ILS / NO
	(total = 24wks) IF I	HCV RNA is reduced 2	og10 and detectable (≥	
	50IU/mL).			
	• ,,		at 24 wks, additional 56wks	
	(total = 72wks) ma			
	, ,	OR bridging fibrosis,	cirrhosis OR HIV co-infection,	
	approve 48wks.			
	☐ Genotype 2, 3, app			
	☐ Genotype 3 AND s	teatosis AND HCV ≥ 6	00,000 IU/mL, approve 48wks.	



	Hepatitis B: (one of the following 4 scenarios must be met) 1. HBV DNA ≥ 20,000IU/mL AND ALT ≥ 2x ULN OR moderate-severe inflammation/fibrosis 2. HBV DNA between 2,000 - 20,000 IU/mL AND ALT ≥ 1x ULN AND moderate-severe inflammation/fibrosis 3. HBV DNA detectable (≤ 2,000 IU/mL) AND cirrhosis 4. patient requiring HBV prophylaxis due to HIV infection, impending immunosuppressive or cytotoxic Tx.	
Exclusion	☐ Maintenance tx of hep C extending tx to 72 wks or longer (one	
Criteria:	exception for 72 wks for genotype 1 hep C).	YES / NO
Age Restriction:		N/A
Prescriber		N/A
Restrictions:		IN/ C
Coverage	☐ HCV1 = 12 - 72 weeks	
Duration:	☐ HCV4, 5, 6 = 48 weeks	VEC / NO
	☐ HCV2 = 24 weeks	YES / NO
	☐ HCV3 = 24 - 48 weeks	
	☐ HBV = 12 months	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: PEGINTRON

Affected Medications: PEGINTRON REDIPEN®, PEGINTRON®

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB: ID#: Provider:	_ Dx:
Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	Hepatitis C:	
Medical	☐ HCV genotype	
Information:	☐ HCV RNA level	
	□ evidence of compensated liver disease (serum bilirubin ≤ 1.5g/dL, INR	
	WNL, serum albumin ≥ 3.4, platelets WNL, absence of encephalopathy	
	or ascites)	
	□ evidence of active liver disease (elevated LFTs, liver biopsy)	YES / NO
	□ evidence patient is not currently using illicit drugs or alcohol.	
	Hometitis B.	
	Hepatitis B:	
	☐ HBeAg status (positive/negative)☐ HBV DNA level, ALT level or liver biopsy showing active liver disease	
	☐ HBV DNA level should be monitored every 3-6 mos during Tx.	
Appropriate	Hepatitis C:	
Treatment	☐ Patients must have detectable HCV RNA levels	
Regimen &	□ evidence of compensated liver disease	
Other Criteria:	□ evidence of active liver disease	
	□ no evidence of current illicit drug or alcohol abuse	
	☐ Preferred treatment is ribavirin and interferon alfa combination	
	Hepatitis C:	
	☐ Genotype 1, initial approval = 12 wks, subsequent approval is	
	additional 36wks (total = 48wks) IF HCV RNA is reduced 2log10 AND	WEG / NO
	undetectable (≤ 50IU/mL) OR subsequent approval is additional 12wks	YES / NO
	(total = 24wks) IF HCV RNA is reduced 2log10 and detectable (≥	
	50IU/mL).	
	☐ In genotype 1, If HCV RNA undetectable at 24 wks, additional 56wks	
	(total = 72wks) may be approved.	
	☐ Genotype 4, 5 or 6 OR bridging fibrosis, cirrhosis OR HIV co-infection,	
	approve 48wks.	
	☐ Genotype 2, 3, approve 24wks.	
	☐ Genotype 3 AND steatosis AND HCV ≥ 600,000 IU/mL, approve 48wks	



	Hepatitis B: (one of the following 4 scenarios must be met)	
	1. HBV DNA ≥ 20,000IU/mL AND ALT ≥ 2x ULN OR moderate-severe	
	inflammation/fibrosis	
	2. HBV DNA between 2,000 - 20,000 IU/mL AND ALT ≥ 1x ULN AND	
	moderate-severe inflammation/fibrosis	
	3. HBV DNA detectable (≤ 2,000 IU/mL) AND cirrhosis	
	4. patient requiring HBV prophylaxis due to HIV infection, impending	
	immunosuppressive or cytotoxic Tx.	
Exclusion	☐ Maintenance tx of hep C extending tx to 72 wks or longer (one	
Criteria:	exception for 72 wks for genotype 1 hep C).	YES / NO
Age		N/A
Restriction:		IV/A
Prescriber		N/A
Restrictions:		14/71
Coverage	☐ HCV1 = 12 - 72 weeks	
Duration:	☐ HCV4, 5,6 = 48 weeks	VEC / NO
	☐ HCV2 = 24 weeks	YES / NO
	☐ HCV3 = 24 - 48 weeks	
	☐ HBV = 12 months	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: POMALYST

Affected Medications: Pomalyst (Pomalidomide)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Patient has diagnosis of multiple myeloma; AND The patient has received at least TWO prior therapies for multiple myeloma including lenalidomide (Revlimid) and bortezomib (Velcade); AND 	YES / NO
	 Patient has demonstrated disease progression on or within 60 days of completion of last therapy for multiple myeloma 	
Appropriate Treatment Regimen & Other Criteria:	 Pomalyst is used in combination with dexamethasone unless patient is steroid-intolerant. All patients monitored for signs and symptoms of thromboembolism. Female patients of child-bearing potential and male partners are instructed on the importance of proper utilization of appropriate contraceptive methods. 	YES / NO
Exclusion Criteria:	□ Pregnancy	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	 □ Prescribed by or in consultation with an oncologist □ Prescriber must be certified with the Pomalyst REMS program 	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.



PRIVIGEN

Affected Medications: PRIVIGEN (immune globulin)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved ind	ications not otherwi	se excluded from Part D,	CONFIRMATION*
	☐ Chronic Lymphocytic	Leukemia (CLL),		
	☐ Kawasaki syndrome,			YES / NO
	□ Chronic Inflammatory	y Demyleninating Po	yneuorapthy (CIDP)	
	□ Pure red cell aplasia ((PRCA).		
Required	☐ Coverage is provided	for:		
Medical	1) Immune Thromboo	cytopenic Purpura (I	⁻ P)	
Information:	2) Confirmed diagnos	sis of CIDP.		
	3) CLL with a serum Ig	gG < 500 mg/dL or a	history of recurrent bacterial	
	infections.			
	4) Kawasaki syndrom	e in conjunction with	high-dose aspirin.	YES / NO
	5) PRCA secondary to	parvovirus B19 infe	ction.	
	☐ For all indications, pa	tients with any of th	e following risk factors for	
	acute renal failure mu	ust receive the minin	num concentration available	
	of IGIV and the minim	num infusion rate pra	acticable: pre-existing renal	
	insufficiency, diabete	s mellitus, age over (55 years, volume depletion,	
	sepsis, paraproteinen	nia, or receiving con	comitant nephrotoxic drugs.	
Appropriate				
Treatment				N/A
Regimen &				,
Other Criteria: Exclusion		atila a di a a ta 1 a A a a d	history of hymansonsitivity	
Criteria:	=		history of hypersensitivity,	
Critcha	, , ,	•	reaction to human immune	YES / NO
	globulin or product co	omponents, and hyp	erprolinemia.	
Age				N/A
Restriction:				IN/A
Prescriber				N/A
Restrictions:				·
Coverage	☐ Approval = 12 months	s, unless otherwise s	pecified.	YES / NO
Duration:				
*Annrovals require	that all holded regions in t	the 'confirmation' co	lumn he documented in mer	nhar's chart notes



PROLIA

Affected Medications: PROLIA (denosumab)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required Medical Information:	 □ For Treatment of Postmenopausal Osteoporosis: □ Documentation of T Score ≤ -2.5 or FRAX Score indicating Major fracture risk > 20% or HIP Fracture > 3%. □ For Treatment to Increase Bone Mass in Women at High Risk for 	YES / NO
	Fracture Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer: □ Evidence of low bone mass (T-score of -1.0 to -2.5).	
Appropriate Treatment Regimen & Other Criteria:	 □ Prolia may be approved for treatment of postmenopausal osteoporosis □ if the patient has tried an oral or intravenous bisphosphonate (eg, alendronate, risedronate, ibandronate, zoledronic acid [Reclast]) OR □ if the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) OR □ chronic kidney disease OR □ if the patient has multiple osteoporotic fractures in the setting of T-scores less than -3.5. □ For Treatment to Increase Bone Mass in Men at High Risk for Fracture Receiving Androgen Deprivation Therapy Prolia may be approved for males: □ If younger than 70 years: T-score < -1.0 at any location, or a history of osteoporotic fracture. □ Documentation of calcium and Vitamin D treatment required. 	YES / NO
Exclusion Criteria:	 □ Coverage not recommended for anything not listed under Covered Uses. □ A serum 25-hydroxyvitamin D level = 12 ng/mL. □ Concurrent use of bisphosphonate therapy or antineoplastic therapy apart from aromatase inhibitors. 	YES / NO
Age Restriction:	 □ For Treatment to Increase Bone Mass in Men at High Risk for Fracture Receiving Androgen Deprivation Therapy: □ Age > 70 years if normal bone mineral density or no history of fracture. □ > 18 years for all other indications. 	YES / NO



Prescriber Restrictions:		N/A			
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO			
*Approvals require th	*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.				



POLICY NAME: PROMACTA

Affected Medications: PROMACTA (eltrombopag)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB: ID#:	Provider:	Dx:
Covered Uses:	All EDA annuavad indications as	h ath amains and add from Dant D	CONFIRMATION*
Covered Uses:	' '	t otherwise excluded from Part D.	
	☐ Thrombocytopenia due to hepat	titis C virus (HCV)-related cirrhosis.	YES / NO
Required	☐ Cause of thrombocytopenia.		
Medical	Cause of thrombocytopenia.		
Information:			YES / NO
Information:			
Appropriate	☐ For treatment of thrombocytope	enia due to HCV-related cirrhosis	
Treatment	☐ approve to allow for initiati	ion of antiviral therapy	YES / NO
Regimen &			ILS / NO
Other Criteria:			
Exclusion	☐ Use in the management of thror	mbocytopenia in myelodysplastic	
Criteria:	syndrome (MDS).		YES / NO
Age			N/A
Restriction:			IV/A
Prescriber	Treatment of thrombocytopenia du	e to:	
Restrictions:	☐ chronic immune (idiopathic) thr	ombocytopenic purpura (ITP)	
	☐ approve if prescribed or cor	isultation by hematologist	YES / NO
	☐ HCV-related cirrhosis		
	☐ approve if prescribed or con	sultation by gastroenterologist or a	
	physician who specializes in	infectious disease	
Coverage	☐ Approval = 12 months, unless ot	herwise specified.	YES / NO
Duration:			,
*Approvals require	that all bolded regions in the 'confirm	nation' column be documented in mem	ber's chart notes.



POLICY NAME: PROVENGE

Drug Name: PROVENGE (sipuleucel-T)

Effective Date: 07/29/2010
Last Review Date: 09/08/2010
Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
	□ Prostate Cancer (dx: 185 only)	TES / NO
Required documentation:	 □ Documentation of complete & current treatment course required. □ Evidence of metastases to soft tissue or bone □ Testosterone levels □ < 50 ug □ Below lowest level of normal □ Evidence of disease progression □ Two sequential rising PSA levels obtained 2-3 wks apart □ Other: 	YES / NO
Appropriate Treatment Regimen:	□ FDA prescribing guidelines:□ Up to three infusions, generally two weeks apart	YES / NO
Exclusion Criteria:	 □ Prior intolerance or allergic reaction to requested medication □ Concomitant use of other chemotherapy or immunosuppressive therapy 	YES / NO
Age Restriction:		N/A
Provider Restriction:		N/A
Approval Duration:	☐ Approvals = 3 infusions or 2 months	YES / NO
*Approvals require t	hat all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



RANEXA

Affected Medications: RANEXA (ranolazine extended-release tablets)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	☐ Patient has tried, failed and/or been intolerant (continues to have	
Medical Information:	angina symptoms that limits daily activities) to a 30-day trial of the	
information:	following:	
	□ nitrate PLUS a beta blocker or	YES / NO
	□ calcium channel blocker.	125 / 110
	OR	
	☐ Patient has received prior treatment with Ranexa, the patient	
	experienced a decrease in angina frequency since initiating treatment.	
Appropriate		
Treatment		N/A
Regimen &		14/74
Other Criteria:		
Exclusion	☐ Patients with clinically significant hepatic impairment	
Criteria:	☐ Patient is receiving a strong CYP3A inhibitor that prolongs the QT	YES / NO
	interval.	
Age		N/A
Restriction:		IV/A
Prescriber	☐ Cardiologist or affiliated with a cardiology practice	YES / NO
Restrictions:		
Coverage	☐ Intial approval = 3 months	YES / NO
Duration:	☐ Renewal approval = Plan Year	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



REBIF

Affected Medications: REBIF (interferon beta-1a)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	Dx: _	
Covered Uses:		All FDA-approved i	ndications not other	wise excluded from Part D.		IRMATION*
Required Medical						N/A
Information:						•
Appropriate Treatment Regimen & Other Criteria:						N/A
Exclusion Criteria:		Concurrent use of a fingolimod (Gilenya		Extavia, Copaxone, Tysabri,		S / NO
Age						N/A
Restriction: Prescriber Restrictions:		Prescribed by or af specialist.	ter consultation witl	n a neurologist or an MS	YI	ES / NO
Coverage Duration:		Approval = 12 mon	ths, unless otherwis	e specified.	YI	S / NO
*Approvals require	that	t all bolded regions i	n the 'confirmation'	column be documented in I	member's char	t notes.



RELISTOR

Affected Medications: RELISTOR (methylnaltrexone bromide)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	□ All FI	DA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	□ Trea	tment of opioid-induced constipation in a patient with advanced	
Medical	illnes	ss who is receiving palliative care. AND	
Information:	□ Patie	ent demonstrated an inadequate treatment response or	
		erance to a drug regimen of polyethylene glycol 3350 (PEG 3350)	YES / NO
	OR		120 / 110
	□ Patie	ent has a documented contraindication to polyethylene glycol 3350 i 3350).	
Appropriate			
Treatment			NI/A
Regimen &			N/A
Other Criteria:			
Exclusion	☐ Knov	wn or suspected mechanical gastrointestinal obstruction.	YES / NO
Criteria:			11.5 / 110
Age			N/A
Restriction:			IN/A
Prescriber			N/A
Restrictions:			IN/A
Coverage	□ Appr	roval = 6 months, unless otherwise specified.	YES / NO
Duration:			
*Approvals require	hat all bo	olded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: REMICADE

Affected Medications: REMICADE (infliximab)

Member:	 DOB:	ID#:	Provider:	Dx:
Covered Uses:	All FDA-approved in	ndications not other	wise excluded from Part D.	CONFIRMATION*
	Patients already sta	rted on infliximab f	or covered uses.	
	Juvenile Idiopathic	Arthritis (JIA)		
	Behcet's disease (BI	D)		YES / NO
	Uveitis (UV)			
	Pyoderma gangreno	osum (PG)		
	Hidradenitis suppur	ativa (HS)		
	Graft-versus-host d	isease (GVHD)		
	Celiac Sprue			
	Wegener Granulom	atosis		
Required	FDA approved indic	ation must be docu	mented in the member's chart	
Medical	notes within the mo	ost recent 6 months		
Information:	Documentation of o	complete and curre	nt treatment course required.	
	For treatment of RA	A: Laboratory test m	ust confirm diagnosis of	
	Rheumatoid Arthrit	is: Anti-Cyclic Citrul	linated Peptide Antibody(anti-	
	CCP) OR Rheumatoi	d Factor (RF).		N/A
	Negative Latent TB	screening with eith	er by TB skin test or an	
	interferon gamma r	elease assay (e.g., 0	QFT-GIT, T-SPOT.TB) prior to	
	request. OR			
	For positive latent 1	B, patient must have	ve completed or receiving	
	treatment for LTBI.			
Appropriate	RA/JIA:			
Treatment	□ pt tried at leas	t 1 oral DMARDs (h	ydroxychloroquine, leflunomid	е,
Regimen & Other Criteria:		minocycline, metho	·	
Other Criteria.		_	s adalimumab, etanercept)	
	Psoriatic Arthritis (-		
	•	• •	droxychloroquine, leflunomide	
		minocycline, metho	•	YES / NO
		-	s adalimumab, etanercept)	
	Ankylosing Spondy	• •		
	•	st 1 oral treatment	•	
	, ,	•	sulfasalazine, minocycline,	
	methotrexate)			
	□ at least 1 biolo	gic DMARD (such a	s adalimumab, etanercept).	



	Plaque psoriasis (PP):	
	$\ \square$ pt has tried at least 1 oral systemic therapy (methotrexate,	
	cyclosporine, isotretinoin) OR	
	□ phototherapy (UVB, PUVA) AND	
	$\ \square$ at least one biologic DMARD (such as adalimumab, etanercept)	
	Crohn's Disease (CD):	
	☐ Pt has tried at least 1 oral treatments for at least 12 weeks	
	(corticosteroids, azathioprine, cyclosporine, 6-mercaptopurine,	
	MTX, tacrolimus, sulfasalazine, mesalamine or balsalazide) AND	
	$\hfill \square$ at least 1 biologic DMARD (such as adalimumab), unless indicated	
	for pediatric Crohn's	
	Ulcerative colitis (UC):	
	☐ Pt has tried at least 2 oral treatments for at least 12 weeks	
	(corticosteroids, azathioprine, cyclosporine, 6-mercaptopurine,	
	MTX, tacrolimus, sulfasalazine, mesalamine or balsalazide)	
	Behcet's Disease (BD):	
	$\ \square$ Pt has not responded to 1 conventional tx (eg, systemic CS,	
	immunosuppressant (eg, AZA, MTX, mycophenolate mofetil	
	(MM), CSA, tacrolimus, chlorambucil, cyclophosphamide (CPM),	
	or interferon alfa), etanercept or adalimumab	
	Uveitis (UV):	
	□ pt has tried periocular/intraocular CS, systemic CS,	
	immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept,	
	adalimumab	
	Pyoderma Gangrenosum (PG):	
	□ pt has tried 1 systemic tx (eg, systemic CS, immunosuppressant	
	(eg, AZA, 6MP, CSA, CPM, chlorambucil), etanercept or	
	adalimumab) for 2 months, or 2-month trial of intralesional CS or	
	CSA for localized PG	
	Hidradenitis Supperativa (HS):	
	□ pt has tried 1 tx (eg, intralesional/oral CS, topical or systemic	
	antibiotic, isotretinoin)	
	Graft Versus Host Disease (GVHD):	
	pt has tried 1 tx (eg, high-dose CS, antithymocyte globulin, CSA,	
	thalidomide, tacrolimus, MM, etc.) or receiving IFB concurrently.	
Exclusion	Concurrent use of: abatacept (Orencia), rituximab(Rituxin),	
Criteria:	tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel),	
	infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi).	YES / NO
	Positive test for tuberculosis, active HZV, HCV or HBV.	,



Age	□ RA, PP, PsA, AS: Adults.	YES / NO		
Restriction:				
Prescriber	☐ CD, UC: in consultation with a GI specialist.	YES / NO		
Restrictions:	☐ PP: in consultation with a dermatologist.			
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO		
Duration:				
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.				



POLICY NAME: REMODULIN

Affected Medications: REMODULIN (treprostinil sodium)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved inc	lications not otherwis	se excluded from Part D.	CONFIRMATION*
	☐ Patients currently on			YES / NO
Required	Pulmonary arterial hyper	tension (PAH)		
Medical	☐ patients not currentl	y on Remodulin must	have a right-heart	
Information:	catheterization to co	nfirm the diagnosis o	f PAH to ensure appropriate	YES / NO
	medical assessment	_		,
	□ patients currently on	Remodulin may con	inue therapy if they have a	
	diagnosis of PAH, acu	•	• • • •	
Appropriate	-		e mean pulmonary artery	
Treatment	pressure at least 25n		, pa pa	
Regimen &	□ at least 30 mm Hg wi	-		YES / NO
Other Criteria:			t (calcium channel blockers,	
	·		contraindicated or patient's	120 / 110
	severity warrants init	•	•	
	Severity warrants iiii	tiai treatinent with N	eniouuiii.	
Exclusion	☐ Coverage is not reco	mmended for circum	stances not listed in the	
Criteria:	Covered Uses.	inneriaed for eneum	stances not noted in the	YES / NO
Age	☐ PAH: Adults			YES / NO
Restriction:				
Prescriber	☐ PAH: In consultation	with a cardiologist or	a pulmonologist.	YES / NO
Restrictions:				_
Coverage	☐ Approval = 12 month	IS.		YES / NO
Duration:				
*Approvals require	that all bolded regions in	the 'confirmation' co.	lumn be documented in memb	per's chart notes.



REVATIO

Affected Medications: REVATIO (sildenafil)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ Infants with pulmonary arterial hypertension (PAH).	YES / NO
Required	□ NYHA Functional Class II or III symptoms.	
Medical	☐ PAH (WHO Group 1) was confirmed by right heart catheterization OR	
Information:	□ by Doppler echocardiography for infants with any of the following	
	conditions:	
	1) post cardiac surgery,	
	2) chronic heart disease,	VEC / NO
	3) chronic lung disease associated with prematurity,	YES / NO
	4) congenital diaphragmatic hernias.	
	☐ For new starts only: patient has had an inadequate response or	
	intolerance to Adcirca (tadalafil).	
	☐ For Revatio injection: patient was previously receiving Revatio tablets	
	but is now temporarily unable to take oral medications.	
	, ,	
Appropriate		
Treatment		N/A
Regimen &		,
Other Criteria: Exclusion	Deticat as a single without the areas of a second of a single was interesting to	
Criteria:	☐ Patient requires nitrate therapy on a regular or intermittent basis.	YES / NO
Age		
Restriction:		N/A
Prescriber		N1/A
Restrictions:		N/A
Coverage	☐ Revatio tablets = 12 months	VEC / NO
Duration:	☐ Revatio injection = 3 months OR unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



REVLIMID

Affected Medications: REVLIMID (lenalidomide)

Effective Date: 01/01/2014
Last Review Date: 08/14/2013
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	□ chronic lymphocytic leukemia (CLL),	
	☐ myelodysplastic syndromes (MDS) without the deletion 5q,	YES / NO
	□ progressive solitary plasmacytoma or smoldering myeloma that has	
	progressed to active/symptomatic	
	□ systemic light chain amyloidosis, and	
	□ the following subtypes of non-Hodgkin's lymphomas (NHL):	
	☐ AIDS-related diffuse large B-cell lymphoma (DLBCL),	
	☐ AIDS-related lymphoma associated with Castleman's disease,	
	☐ AIDS-related primary effusion lymphoma,	
	□ DLBCL,	
	□ follicular lymphoma (FL),	
	☐ gastric mucosa associated lymphoid tissue (MALT) lymphoma,	
	□ mantle cell lymphoma (MCL),	
	□ nodal marginal zone lymphoma,	
	□ nongastric MALT lymphoma, primary cutaneous B-cell lymphoma	
	(PCBCL), and	
	□ splenic marginal zone lymphoma.	
Required	Active/symptomatic myeloma or progressive solitary plasmacytoma,	
Medical	☐ Revlimid is warranted in any of the following settings:	
Information:	 □ a) Revlimid is used as primary induction therapy in 	
	combination with dexamethasone or both melphalan and	
	prednisone,	
	□ b) Revlimid is used as maintenance monotherapy for patients	
	responding to primary induction therapy or for patients with	
	stable or responsive disease following stem cell transplant,	YES / NO
	☐ c) Revlimid is used as salvage or palliative therapy.	ILS / NO
	Low or intermediate-1 risk MDS,	
	☐ Revlimid is warranted in any of the following settings:	
	☐ a) In those with a 5q deletion, patients have transfusion-	
	dependent anemia (i.e., greater than 2 units of red blood cells	
	in the previous 8 weeks) or symptomatic anemia,	
	☐ b) In those without a 5q deletion and symptomatic anemia,	
	patients have pretreatment serum erythropoietin level greater	



	than 500 mU/mL or both a pretreatment serum erythropoietin	
	level less than or equal to 500 mU/mL and have failed a trial of	
	epoetin or darbepoetin.	
	NHL,	
	Revlimid is warranted in any of the following settings:	
	☐ Revlimid is used in relapsed or refractory disease in patients	
	with CLL,	
	☐ Revlimid is used as monotherapy or in combination with	
	rituximab for relapsed, refractory, or progressive disease in the	
	following subtypes of NHL:	
	☐ AIDS-related DLBCL,	
	☐ AIDS-related lymphoma associated with Castleman's disease,	
	☐ AIDS-related primary effusion lymphoma,	
	□ DLBCL,	
	□ FL,	
	☐ gastric MALT lymphoma,	
	□ MCL,	
	nodal marginal zone lymphoma,	
	□ nongastric MALT lymphoma,	
	□ PCBCL,	
	 splenic marginal zone lymphoma. 	
	Systemic light chain amyloidosis,	
	☐ Revlimid is used in combination with dexamethasone as	
	primary therapy.	
	MCL	
	☐ disease has relapsed or progressed after two prior therapies, one of	
	which included bortezomib.	
	 Female patients of child-bearing potential, pregnancy is excluded by two negative serum or urine pregnancy tests. 	
	☐ Complete blood counts are regularly evaluated for hematological	
	toxicity.	
Appropriate	☐ All patients are monitored for signs and symptoms of	
Treatment	thromboembolism.	
Regimen &	☐ Female patients of child-bearing potential and male patients are	YES / NO
Other Criteria:	instructed on the importance and proper utilization of appropriate	1 = 2 ,
	contraceptive methods.	
Exclusion	□ Pregnancy.	VEC / NO
Criteria:		YES / NO
Age		N/A
Restriction:		14/74



Prescriber		N/A	
Restrictions:		IN/A	
Coverage	☐ Approval =12 months, unless otherwise specified.	YES / NO	
Duration:			
*Approvals require	*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.		



POLICY NAME: RISPERDAL CONSTA

Affected Medications: RISPERDAL CONSTA (risperidone)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical	☐ The patient has a history of non-compliance and/or refuses to utilize	
	oral medications.	
Information:	☐ The patient must have a history of 3 test doses of oral Risperdal (risperidone).	YES / NO
	☐ If the patient is increasing the dose of Risperdal Consta the patient has a history of two prior injections of Risperdal Consta.	
Appropriate		
Treatment		NI / A
Regimen &		N/A
Other Criteria:		
Exclusion	☐ Dementia-related psychosis.	VEC. / NO.
Criteria:		YES / NO
Age		N1 / A
Restriction:		N/A
Prescriber	☐ Psychiatrist or receiving input from psychiatry practice	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		,
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



RITUXAN

Affected Medications: RITUXAN (rituximab)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	All EDA approved/medically accounted indications not otherwise	CONFIRMATION*
Covered Uses:	☐ All FDA-approved/ medically-accepted indications not otherwise	CONFIRMATION
	excluded from Part D.	YES / NO
	Patients already started on Rituxan for rheumatoid arthritis (RA).	TES / NO
Required Medical	☐ FDA approved indication must be documented in the member's chart	
Medical Information:	notes within the most recent 6 months.	
Illioi illatioli.	□ Documentation of complete and current treatment course required.	
	☐ For treatment of RA: Laboratory test must confirm diagnosis of	
	Rheumatoid Arthritis: Anti-Cyclic Citrullinated Peptide Antibody(anti-	
	CCP) OR Rheumatoid Factor (RF).	YES / NO
	☐ Negative Latent TB screening with either by TB skin test or an	
	interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) prior to	
	request. OR	
	☐ For positive latent TB, patient must have completed or receiving	
	treatment for LTBI.	
Appropriate	Adult with RA	
Treatment	Initial course:	
Regimen &	☐ Patient has failed at least 12 weeks of therapy of at least 2 DMARDs	
Other Criteria:	(hydroxychloroquine, leflunomide, methotrexate, minocycline,	
	sulfasalazine) AND	
	☐ Patient has failed at least 12 weeks of therapy of another biologic	
	agent [abatacept (Orencia), rituximab(Rituxin), tocilizumab(Actemra),	
	adalimumab (Humira), entanercept(Enbrel), infliximab(Remicade),	VEC / NO
	certolizumab(Cimzia), golimumab(Simponi)]	YES / NO
	Repeat course:	
	approve if 16 weeks or more after the first dose of the previous	
	rituximab regimen and the patient has responded (eg, less joint pain,	
	morning stiffness, or fatigue, or improved mobility, or decreased soft	
	tissue swelling in joints or tendon sheaths) as determined by the	
	prescribing physician.	
Exclusion	☐ Concurrent use of: abatacept (Orencia), rituximab(Rituxin),	
Criteria:	tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel),	YES / NO
	infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi).	, ,
Age	□ RA, adults.	YES / NO
Restriction:	,	, -



Prescriber		Adult with RA (initial and repeat courses). Prescribed by a	
Restrictions:		rheumatologist or in consultation with a rheumatologist.	
		Non-RA indications, if prescribed by or in consultation with an	YES / NO
		oncologist, hematologist, neurologist, multiple sclerosis (MS) specialist,	
		rheumatologist, dermatologist, or immunologist, or who are being	
		managed by a transplant center.	
Coverage		RA: Approval =2 doses.	
Duration:		16 wks or more after, approve 2 more doses if response per doctor.	YES / NO
		Other indications = 12 months	
*Approvals require	that	t all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



SAMSCA

Affected Medications: SAMSCA (Tolvaptan Tablets)

Effective Date: 01/01/2014
Last Review Date: 9/23/2012
Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:		ly started on tolvaptan f	rwise excluded from Part D or the treatment of	CONFIRMATION* YES / NO
Required Medical Information:	defined as seru		or less marked hyponatremia, at baseline, that is symptomatic rgy, confusion).	YES / NO
Appropriate Treatment Regimen & Other Criteria:	hyponatremia marked hypon	with serum sodium < 12 atremia, defined as < 13	nt hypervolemic and euvolemic 5 mEq/L at baseline or less 5 mEq/L at baseline, that is adache, lethargy, confusion).	YES / NO
Exclusion Criteria:	•	ing intervention to raise reat serious neurologica	serum sodium urgently to I symptoms.	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Approval = 12	months.		YES / NO
*Approvals require	that all bolded region	ons in the 'confirmation'	column be documented in mem	ber's chart notes.



POLICY NAME: SANDOSTATIN LAR

Affected Medications: SANDOSTATIN LAR DEPOT

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	□ atypical lung carcinoids,	
	□ islet cell tumors,	YES / NO
	☐ multiple endocrine neoplasia type 1 (MEN 1).	
Required	Acromegaly therapy	
Medical	☐ Initiation of therapy, patient meets the following:	
Information:	1) Clinical evidence of acromegaly,	
	2) Pre-treatment high IGF-1 level for age/gender,	
	3) Patient has had an inadequate or partial response to surgery	
	and/or radiotherapy OR	
	□ there is a clinical reason for why the patient has not had surgery or	
	radiotherapy (e.g., medically unstable conditions, patient is at high	
	risk for complications of anesthesia because of airway difficulties,	
	lack of an available skilled surgeon, patient refuses surgery or prefers	
	the medical option over surgery, major systemic manifestations of	
	acromegaly including cardiomyopathy, severe hypertension and	YES / NO
	uncontrolled diabetes).	, , , , ,
	☐ Continuation of therapy, the IGF-1 level decreased or normalized.	
	Atypical lung carcinoids, use in combination with chemotherapy.	
	Islet cell tumors, patient has insulinoma, glucagonoma, or VIPoma.	
	Multiple endocrine neoplasia type 1 (MEN 1) patient meets one of the	
	following:	
	1) Patient has insulinoma, glucagonoma, or VIPoma OR	
	2) Patient has pituitary adenoma and is symptomatic or has	
	significant tumor burden.	
	☐ Patient received at least 2 weeks of initial treatment with	
	Sandostatin Injection (not the Depot formulation) and treatment	
	with Sandostatin Injection was effective and tolerable.	
Appropriate		
Treatment		N/A
Regimen &		N/A
Other Criteria:		
Exclusion		N/A
Criteria: Age Restriction:		
Age Restriction:		N/A
İ		



Prescriber Restrictions:		N/A	
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO	
Duration:			
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.			



POLICY NAME: SEROSTIM

Affected Medications: SEROSTIM (somatropin)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:		All FDA-approved i	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:		with HIV infection. Serostim is used in Alternative causes malabsorption, oppruled out or treate Prior to somatropin other therapy for volumless contraindicate For continuation of	combination with a of wasting (eg, inade portunistic infections d appropriately. In, patient had a subovasting or cachexia (extended or not tolerated f therapy: Patients to demonstrated a response.	vasting syndrome associated ntiretroviral therapy. equate nutrition intake, s, hypogonadism) have been optimal response to at least 1 eg, megestrol or dronabinol). eated with Serostim for 12 oonse to therapy (ie, body ma	YES / NO
Appropriate Treatment Regimen & Other Criteria: Exclusion		Acute exitical illage	a active malignance		N/A
Criteria:		Acute critical llines	s, active malignancy		YES / NO
Age Restriction:					N/A
Prescriber Restrictions:					N/A
Coverage Duration:		Approval =12 week	<u></u>		YES / NO
*Approvals require	*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.				



SIGNIFOR

Affected Medications: SIGNIFOR (pasireotide diaspartate)

Effective Date: 03/01/2014
Last Review Date: 09/23/2013
Part D: Yes Part B: No

Member:	DOB:	ID#:	Provider:	_ Dx:
				<u></u>
Covered Uses:	☐ All FDA-approved ind	ications not otherw	ise excluded from Part D.	CONFIRMATION*
				YES / NO
Required	☐ HbA₁C (within 3 mont	ths)		
Medical	☐ Liver function tests (v	within 3 months)		VEC / NO
Information:	☐ Ultrasound of gallbla	dder (within 3 mont	hs)	YES / NO
	☐ EKG (within 3 months		•	
	,	,		
Appropriate	☐ Provide documentati	on of failure or inab	ility to receive curative	
Treatment	surgery		,	
Regimen &	o ,	on of failure or inab	ility to receive ketoconazole or	YES / NO
Other Criteria:	metyrapone	on or randre or mas	mey to receive Recognization	
Other Criteria.	metyrapone			
Exclusion	☐ Poorly controlled dia	betes mellitus (HbA	C>8%)	
Criteria:	☐ Severe hepatic impai	rment (Child Pugh C)	YES / NO
Age	☐ Age > 18 years.			YES / NO
Restriction:				
Prescriber	☐ Endocrinologist or in	collaboration with a	n endocrinology practice	YES / NO
Restrictions:				120 / 110
Cavarage		.1	-1-1	NEG / NO
Coverage	☐ Approval = 6 months	unless otherwise sta	ated	YES / NO
Duration:				
*Approvals require	that all bolded regions in a	the 'confirmation' co	olumn be documented in memb	er's chart notes.



SIMPONI

Affected Medications: SIMPONI (golimumab)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION*
	□ Patients already started on golimumab for a covered use.	YES / NO
Required	☐ FDA approved indication must be documented in the member's chart	
Medical	notes within the most recent 6 months.	
Information:	□ Documentation of complete and current treatment course required.	
	☐ For treatment of RA: Laboratory test must confirm diagnosis of	
	Rheumatoid Arthritis: Anti-Cyclic Citrullinated Peptide Antibody(anti-	
	CCP) OR Rheumatoid Factor (RF).	YES / NO
	□ Negative Latent TB screening with either by TB skin test or an	
	interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) prior to	
	request. OR	
	☐ For positive latent TB, patient must have completed or receiving	
	treatment for LTBI.	
Appropriate	Rheumatoid Arthritis (RA):	
Treatment	□ Patient has failed at least 12 weeks of therapy of at least 2	
Regimen &	DMARDs (hydroxychloroquine, leflunomide, methotrexate,	
Other Criteria:	minocycline, sulfasalazine) AND	
	☐ Patient has failed at least 12 weeks of therapy of another biologic	
	agent [abatacept (Orencia), rituximab(Rituxin),	
	tocilizumab(Actemra), adalimumab (Humira),	
	entanercept(Enbrel), infliximab(Remicade), certolizumab(Cimzia),	
	golimumab(Simponi)]	
	Psoriatic Arthritis (PsA):	YES / NO
	☐ pt tried at least 1 oral DMARD (hydroxychloroquine, leflunomide,	
	sulfasalazine, minocycline, methotrexate) AND	
	☐ at least 1 biologic DMARD (such as adalimumab, etanercept)	
	Ankylosing Spondylitis (AS):	
	□ pt tried at least 1 oral treatment (corticosteroids,	
	hydroxychloroquine, leflunomide, sulfasalazine, minocycline,	
	methotrexate) AND	
	☐ at least 1 biologic DMARD (such as adalimumab, etanercept)	
Exclusion	☐ Concurrent use of abatacept (Orencia), rituximab(Rituxin),	
Criteria:	tocilizumab(Actemra), adalimumab (Humira), entanercept(Enbrel),	YES / NO
	infliximab(Remicade), certolizumab(Cimzia), golimumab(Simponi).	125 / 110
	☐ Management of plaque psoriasis without psoriatic arthritis.	



Age	☐ Rheumatoid arthritis (RA), adults.	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		N/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



SIRTURO

Affected Medications: SIRTURO (bedaquiline fumarate)

Effective Date: <u>03/01/2014</u> Last Review Date: <u>09/23/2013</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:		indications not other drug resistant tubercu	wise excluded from Part D. Ilosis (MDR-TB).	CONFIRMATION* YES / NO
Required Medical Information:	combination of the fold Isoniazid Rifampin Ethambutol Pyrazinamide Fluoroquinolone	lowing: amycin,Amikacin, Str hinamide done	to quad therapy of any eptomycin	YES / NO
Appropriate Treatment Regimen & Other Criteria:	(DOT) Baseline ECG	-	by directly observed therapy	YES / NO
Exclusion Criteria:		(DS-TB) le to <i>Mycobacterium</i> B (e.g., central nervol		YES / NO
Age Restriction:	☐ Age > 18 years.			YES / NO
Prescriber Restrictions:	☐ Endocrinologist or	in collaboration with	an endocrinology practice	YES / NO
Coverage Duration:		eks unless otherwise	stated	YES / NO



SOLARAZE

Affected Medications: SOLARAZE (diclofenac sodium)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	ndications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:	management of Bo imiquimod, cryother laser, or radiothera DSAP, approve Solaraze a the management of Bo imiquimod, cryothera and corticosteroid, top	owen's disease (eg, to erapy, photodynamic apy). after a trial of at least of DSAP (eg, topical 5-	one other therapy used for the pical 5-fluorouracil [5-FU], therapy, curettage, excision, two other therapies used for FU, imiquimod, topical gues, topical or oral retinoid, diaser).	YES / NO
Exclusion Criteria:	alopecia areata).	ent of cosmetic conditent of osteoarthritis.	ions (e.g., liver spots, wrinkles	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Approval = 12 mon	nths, unless otherwise	specified.	YES / NO
*Approvals require	that all bolded regions i	n the 'confirmation' o	olumn be documented in mei	mber's chart notes.



SOLIRIS

Affected Medications: SOLIRIS (eculizumab)

Effective Date: 04/01/2010
Last Review Date: 02/10/2010
Part D: No Part B: Yes

Covered Uses:	☐ All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required Medical Information:	 □ Documentation of complete & current treatment course required. □ Confirmed diagnosis using: □ Flow Cytometric Immunophenotyping □ ≥ 4 blood transfusions required in previous 12 months □ Administration of quadravalent, conjugated meningococcal vaccination ≥ 2wks prior to Tx must be documented □ Documentation of initial LDH level: □ Documentation of initial Hb level: 	YES / NO
	□ Soliris OneSource can be reached at 1-888-765-4747	
Appropriate Treatment Regimen & Other Criteria:	 □ Subsequent approval requires documentation of treatment success. □ LDH, □ Hb, □ blood transfusion hx, □ infusion records □ current chart notes required 	YES / NO
Exclusion Criteria:	 □ Prior intolerance or allergic reaction to requested medication. □ Current meningitis infection or lack of meningococcal vaccination □ Other serious infections 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:	☐ Hematologist or oncologist	YES / NO
Coverage Duration: *Approvals require	☐ Initial Approval = 3 months ☐ Subsequent approval = 6 months ethat all bolded regions in the 'confirmation' column be documented in members.	YES / NO



POLICY NAME: SOMATULINE DEPOT

Affected Medications: SOMATULINE DEPOT (lanreotide)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Patient meets the following criteria for initiation of therapy: Clinical evidence of acromegaly, Pre-treatment high IGF-1 level for age/gender, and Patient has had an inadequate or partial response to surgery and/or radiotherapy OR There is a clinical reason for why the patient has not had surgery or radiotherapy (e.g., medically unstable conditions, patient is at high risk for complications of anesthesia because of airway difficulties, lack of an available skilled surgeon, patient refuses surgery or prefers the medical option over surgery, major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes). For continuation of therapy, the IGF-1 level decreased or normalized. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion		N/A
Criteria:		N/A
Restriction:		11/ 🔼
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise noted.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	r's chart notes.



POLICY NAME: SOMAVERT

Affected Medications: SOMAVERT (pegvisomant)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION* YES / NO
Required Medical Information:	 □ Patient meets the following criteria for initiation of therapy: Clinical evidence of acromegaly, Pre-treatment high IGF-1 level for age/gender, Patient has had an inadequate or partial response to octreotide or lanreotide OR patient is intolerant to or has a contraindication to octreotide or lanreotide, and Patient has had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy (e.g., medically unstable conditions, patient is at high risk for complications of anesthesia because of airway difficulties, lack of an available skilled surgeon, patient refuses surgery or prefers the medical option over surgery, major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes). □ For continuation of therapy, the IGF-1 level decreased or normalized. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:		N/A
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise noted.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: SORIATANE

Affected Medications: SORIATANE (Acitretin)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

		CONFIDMATION
Covered Uses:	All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION*
	Prevention of non-melanoma skin cancers in high risk individuals	YES / NO
Required	If the patient is female and able to bear children (e.g., no	
Medical	hysterectomy, not reached menopause, has achieved menses). AND	
Information:	The patient is unresponsive to other therapies for the covered	
	diagnoses OR the other therapies for the treatment of the covered	
	diagnoses are contraindicated due to the clinical condition of the	
	patient. AND	
	Pregnancy has been excluded as confirmed by 2 negative urine or	
	serum pregnancy tests with a sensitivity of at least 25 mIU/mL. AND	
	the patient has chosen to use any of the following methods of	
	contraception: one primary form (e.g., tubal ligation, partner's	
	vasectomy, intrauterine devices, birth control pills,	
	injectable/implantable/insertable/topical hormonal birth control	YES / NO
	products) plus one secondary form (e.g., diaphragms, latex condoms,	
	cervical caps) used in combination with a spermicide OR absolute	
	abstinence. AND	
	The patient has agreed to use her chosen form of contraception for at	
	least 1 month before initiation of Soriatane therapy, during Soriatane	
	therapy, and for at least 3 years after discontinuation of therapy. AND	
	The patient has been advised that ethanol must not be ingested by	
	female patients during Soriatane treatment and for 2 months following	
	therapy. AND	
	The patient will have a negative pregnancy test on a monthly basis.	
Appropriate		
Treatment	Female patient or guardian signed a Patient Agreement/Informed	YES / NO
Regimen &	Consent.	
Other Criteria:		
Exclusion	Severely impaired liver function.	
Criteria:	Severely impaired kidney function.	
	Chronic abnormally elevated blood lipid values.	YES / NO
	Currently taking methotrexate or tetracycline.	
Age		N/A
Restriction:		N/A



Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



SOVALDI

Affected Medications: SOVALDI (Sofosbuvir)

Effective Date: <u>08/01/2014</u> Last Review Date: <u>06/11/2014</u>

Covered Uses:	☐ All FDA approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required Medical Information:	 □ Documented genotype chronic hepatitis C virus (HCV) OR hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) AND □ Documentation of liver disease (including cirrhosis) with Child-Pugh Classification □ Fibrosis Staging □ Documentation if patient is Treatment-naïve, prior relapse, or prior partial responder □ Creatinine Clearance: calculated by Serum Creatinine, Age, Weight 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	Genotype 1, 3, 4 Sovaldi 12 weeks AND Must be used in combination with peginterferon alfa and ribavirin. If peginterferon alfa or ribavirin is permanently discontinued then Sovaldi must also be discontinued. Genotype 1 Documentation of contraindication to Interferon. Sovaldi 12 weeks AND Must be used in combination with: Simeprevir Genotype 2 Sovaldi 12 weeks AND Must be used in combination with ribavirin Genotype 3 (non-preferred regimen see LONESTAR-2) Must have documentation of contraindication to Interferon. Sovaldi 24 weeks AND Must be used in combination with ribavirin Contraindication to Interferon is defined by one of the following conditions: Autoimmune hepatitis or other autoimmune disorder, hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic patients before treatment, major depression disorder with suicidal ideation – patient must have evaluation done by Psychologist within the 6 months of initiation of therapy,	YES / NO



	□ bipolar disorder,	
	□ baseline neutrophil count <1,500/μL,	
	baseline platelet count of < 90,000/μL,	
	☐ Preexisting cardiac disease (prior history of MI or stent placement)	
	Patients with Hepatocellular Carcinoma Awaiting Liver Transplantation Sovaldi (maximum 48 weeks) AND Must be used in combination with ribavirin	
Exclusion	□ eGFR <30mL/min or requiring hemodialysis	
Criteria:	☐ Concomitant use of: carbamazepine, phenytoin, phenobarbital,	YES / NO
	oxcarbazepine, tipranavir or ritonavir	
Age	☐ 18 years of age or older	YES / NO
Restriction:		
Prescriber	☐ Hepatologist, Gastroenterologist, ID Specialist	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 weeks (maximum of 24 weeks)	YES / NO
Duration:	☐ Awaiting Liver Transplant: until date of transplant up to 48 weeks	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



SPRYCEL

Affected Medications: SPRYCEL (dasatinib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	_ Dx:
Covered Uses:	☐ All medically-accepte	ed indications not other	erwise excluded from Part D.	CONFIRMATION*
	☐ Patients already star			YES / NO
Required	☐ Diagnosis for which S	Sprycel is being used.		
Medical	☐ For indications of CM	1L and ALL, the Philad	elphia chromosome (Ph)	
Information:	status of the leukem	ia must be reported.		YES / NO
	☐ New patients with CI	ML and ALL which is P	n-positive may receive	
	authorization for Spr	ycel.		
Appropriate	Chronic myeloid leukemi	a (CML)		
Treatment	☐ new patient must ha	ve Ph-positive CML fo	r approval of Sprycel.	
Regimen &	·	·		
Other Criteria:	Acute lymphoblastic leuk	cemia (ALL)		YES / NO
	□ new patient must ha	ve Ph-positive ALL for	approval of Sprycel.	
	·	·		
Exclusion	☐ New patients with ch	ronic myeloid leukem	ia (CML) which is	
Criteria:	Philadelphia chromo	some (Ph)-negative.		
	☐ New patients with CI	ML whose Ph status is	unknown.	
	☐ New patients with a	cute lymphoblastic leu	kemia (ALL) which is Ph-	YES / NO
	negative.			
	☐ New patients with A	LL whose Ph status is (ınknown.	
Age				N/A
Restriction:				IV/A
Prescriber				N/A
Restrictions:				,
Coverage	☐ Approval = 12 month	is, unless otherwise n	oted.	YES / NO
Duration:				
*Approvals require	that all bolded regions in	the 'confirmation' col	ımn be documented in memb	er's chart notes.



STELARA

Affected Medications: STELARA (ustekinumab)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Member:	 DOB:	ID#:	Provider:	Dx:
Covered Uses:	• •	indications not other tarted on ustekimuma	wise excluded from Part D. ab for a covered use.	CONFIRMATION* YES / NO
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:	tried a systemic the following: MTX, cy phototherapy, AN plaque psoriasis. Exceptions allowed plaque psoriasis of areas or genitalia (if they've had an it therapy with one of AND has tried a TNF and has significant disafunctioning according according according to the following	mum body surface ar nerapy OR phototherally closporine, acitreting D has tried adalimum d for patients with less f palms, soles, head a OR inadequate response of the following: MTX tagonist (adalimum abability or impairment ding to the treating phave contraindications eptions can be evaluated.	, ,	e
Exclusion Criteria:	factor (TNF) antag etanercept, golimu Use in the manage	conist (eg, adalimuma umab, infliximab), wit ement of psoriatic art	mbination with a tumor necrosi b, certolizumab pegol, th anakinra, or with alefacept. hritis without plaque psoriasis. ase, or multiple sclerosis.	YES / NO
Age Restriction:	Adults			YES / NO



Prescriber	☐ Prescribed by or in consultation with a dermatologist.	YES / NO
Restrictions:		
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.		



SUTENT

Affected Medications: SUTENT (sunitinib malate)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	□ thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary),	
	☐ lung neuroendocrine tumors,	YES / NO
	□ angiosarcoma,	
	□ solitary fibrous tumor,	
	□ hemangiopericytoma.	
Required	☐ RCC, patient has advanced RCC.	
Medical	☐ GIST : patient had disease progression on imatinib or was intolerant	
Information:	to imatinib.	
	☐ PNET s: patient has well differentiated tumors and progressive	
	unresectable locally advanced or metastatic disease.	
	☐ LNETs : tumors are low or intermediate grade (typical or atypical	
	carcinoid) and patient has unresectable or advanced disease (stage	
	IIIb-IV).	
	☐ Follicular, papillary, or Hurthle cell thyroid carcinoma: patient has	YES / NO
	clinically progressive or symptomatic metastatic disease with	
	nonradioiodine-responsive tumors at sites other than central	
	nervous system.	
	☐ Medullary thyroid carcinoma : patient has disseminated	
	symptomatic disease with progression on vandetanib or vandetanib	
	is not appropriate.	
	☐ Angiosarcoma, solitary fibrous tumor, or hemangiopericytoma:	
	Sutent will be used as a single agent.	
Appropriate	☐ Patient will be monitored for signs and symptoms of CHF.	
Treatment	☐ Liver function test monitoring at initiation of therapy and throughout	
Regimen &	treatment.	YES / NO
Other Criteria:	☐ Sutent therapy will be interrupted for serious hepatic adverse events	,
	and discontinued if serious hepatic adverse events do not resolve.	
Exclusion	☐ Clinical manifestations of congestive heart failure (CHF).	VEC. / NO
Criteria:		YES / NO
Age Restriction:		N/A
Prescriber		N/A
Restrictions:		·
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require th	at all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: SYLATRON

Affected Medications: SYLATRON (peginterferon alfa-2b)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	☐ Chronic myelogenous leukemia (CML)	YES / NO
Required	Melanoma:	
Medical Information:	☐ must have microscopic or gross nodal involvement and had a surgical resection of the tumor including complete lymphadenectomy.	
	CML:	YES / NO
	 patient unable to tolerate a tyrosine kinase inhibitor (eg, imatinib, dasatinib, or nilotinib) or post-transplant patient without remission or with relapse. 	
Appropriate Treatment Regimen & Other Criteria:	 □ Patients will be monitored and evaluated for signs and symptoms of depression and other psychiatric symptoms throughout treatment. □ For melanoma, Sylatron must be requested within 84 days (12 weeks) of the surgical resection. 	YES / NO
Exclusion Criteria:	 □ Autoimmune hepatitis. □ Decompensated hepatic disease. □ Uncontrolled major depression or severe mental illness. 	YES / NO
Age Restriction:		N/A
Prescriber		N/A
Restrictions:		IN/ A
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



SYLVANT

Affected Medications: SYLVANT (siltuximab)

Effective Date: 09/01/2014
Last Review Date: 07/09/2014
Part D: Yes Part B: Yes

Covered Uses: All FDA-approved indications not otherwise excluded from Part D		CONFIRMATION* YES / NO	
			,
Required		The diagnosis was confirmed by biopsy of lymph gland	
Medical		HIV and human herpes virus-I (HHV-8) negative	YES / NO
Information:		Hematology laboratory tests prior to each dose for the first 12 months and every 3 dosing cycles thereafter	
Appropriate		Before first treatment: ANC greater than or equal to 1.0 x10 ⁹ /L,	
Treatment		Platelet count greater than or equal to 75 x10 ⁹ /L, Hemoglobin less	
Regimen &		than 17 g/dL	YES / NO
Other Criteria:		Retreatment: ANC greater than or equal to 1.0×10^9 /L, Platelet count greater than or equal to 50×10^9 /L, Hemoglobin less than 17 g/dL	
Exclusion			N1 / A
Criteria:			N/A
Age		18 years and older	VEC / NO
Restriction:			YES / NO
Prescriber		Oncologist	VEC / NO
Restrictions:			YES / NO
Coverage		Approval = 3 months, unless otherwise noted.	YES / NO
Duration:			
*Approvals require	that	all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



SYMLIN

Affected Medications: SYMLINPEN (pramlintide acetate)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB: ID#: Provider:	Dx:
Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D ☐ patient has type 1 or 2 diabetes mellitus.	CONFIRMATION* YES / NO
Required Medical Information:		N/A
Appropriate Treatment Regimen & Other Criteria:	 □ If patient received Symlin in previous 3 months, patient demonstrated an expected reduction in HbA1c since starting Symlin therapy. OR □ The patient has inadequate glycemic control (HbA1c > 7%). AND □ Patient is currently receiving optimal mealtime insulin therapy. 	YES / NO
Exclusion Criteria:	 Severe hypoglycemia that required assistance during the past 6 months. Gastroparesis. Patient requires drug therapy to stimulate gastrointestinal motility. Hypoglycemia unawareness (i.e., inability to detect and act upon the signs or symptoms of hypoglycemia). HbA1c level greater than 9 percent. Weight loss treatment. 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise noted.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



SYNRIBO

Affected Medications: Synribo (Omacetaxine)

Effective Date: 05/01/2013
Last Review Date: 03/13/2013
Part D: Yes Part B: No

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D	CONFIRMATION*
		YES / NO
Required	☐ All Resistance, intolerance, or contraindication to two or more tyrosine	
Medical	kinase inhibitors (TKIs) must be documented.	VEC / NO
Information:	☐ Examples of prior TKI therapies for CML include imatinib, dasatinib,	YES / NO
	nilotinib, bosutinib, and ponatinib.	
Appropriate		
Treatment		NI/A
Regimen &		N/A
Other Criteria:		
Exclusion	☐ Concurrent use of anticoagulants, aspirin, or NSAIDs when the platelet	
Criteria:	count is <50,000/mm ³ (risk bleeding).	
	☐ Poorly controlled diabetes mellitus.	VEC / NO
	☐ Avoid until good glycemic control has been established.	YES / NO
	☐ Patients with NYHA class III or IV heart disease, active ischemia, or	
	other uncontrolled cardiac conditions.	
Age	☐ Age > 18 years.	YES / NO
Restriction:		TES / NO
Prescriber	☐ Prescribed by or after consultation with an oncologist.	YES / NO
Restrictions:		TES / NO
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



TAFINLAR

Affected Medications: TAFINLAR (dabrafenib mesylate)

Effective Date: <u>09/01/2013</u> Last Review Date: <u>07/26/2013</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required	☐ Unresectable or metastatic melanoma with BRAF V600E mutation	
Medical	detected by FDA approved test	YES / NO
Information:		
Appropriate		
Treatment		
Regimen &		N/A
Other Criteria:		
Exclusion	☐ Combination with Mekinist or Zelboraf	YES / NO
Criteria:		123 / 140
Age	☐ Age > 18 years	YES / NO
Restriction:		
Prescriber		NI/A
Restrictions:		N/A
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		,
*Approvals require	that all bolded regions in the 'confirmation' column be documented in men	nber's chart notes.



TARCEVA

Affected Medications: TARCEVA (erlotinib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required	Non-small cell lung cancer (NSCLC)	
Medical	□ locally advanced or metastatic.	
Information:		
	First line treatment of NSCLC, patient has a known active epidermal	
	growth factor receptor (EGFR) mutation or amplification of the EGFR	
	gene.	
	☐ Second or third line treatment of NSCLC, Tarceva is used as	
	monotherapy.	
	☐ Maintenance treatment of NSCLC, the following criteria are met:	YES / NO
	1) patient responded to or remains stable after four cycles of platinum-	ILS / NO
	based chemotherapy, AND	
	2) Tarceva is being used as monotherapy.	
	Pancreatic cancer, the following criteria are met:	
	1) pancreatic cancer is locally advanced, unresectable or metastatic,	
	AND	
	2) Tarceva is used as first line treatment, AND	
	3) Tarceva is used in combination with gemcitabine.	
Appropriate		
Treatment		N/A
Regimen &		IN/A
Other Criteria:		
Exclusion		N/A
Criteria:		,
Age		N/A
Restriction:		
Prescriber Restrictions:		N/A
Coverage	Approval = 12 months, unless otherwise noted	VEC / NO
Duration:	☐ Approval = 12 months, unless otherwise noted.	YES / NO
	that all bolded regions in the 'confirmation' column be documented in memb	or's chart notes
Approvais require	that an bolueu regions in the commination column be documented in memb	er s criart notes.



POLICY NAME: TARGRETIN

Affected Medications: TARGRETIN (Bexarotene)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	☐ Mycosis fungoides,	
	☐ Sezary Syndrome (Capsules only),	YES / NO
	☐ Adult T-cell leukemia/lymphoma (Gel only), and	
	□ Primary cutaneous B-cell lymphoma (Gel only)	
Required	Targretin Capsule:	
Medical	☐ Patient must meet one of following criteria: received prior systemic	
Information:	therapy for CTCL OR advanced-stage MF (stage IIB, III or IV) or SS OR	
	□ early-stage MF (stage IA, IB or IIA) with folliculotropic/large cell	
	transformation OR	175 / NO
	□ early-stage MF (stage IA, IB or IIA) refractory to skin directed therapy.	YES / NO
	Targretin Gel:	
	☐ Patient must meet one of following criteria for CTCL: early-stage MF	
	(stage IA, IB, or IIA) OR	
	□ stage IIB or III MF in combination with systemic therapy.	
Appropriate		
Treatment	☐ Patient has been instructed on the importance and proper utilization of	YES / NO
Regimen &	appropriate contraceptive methods.	125 / 116
Other Criteria:		
Exclusion	□ Pregnancy.	YES / NO
Criteria:		
Restriction:		N/A
Prescriber		
Restrictions:		N/A
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require	that all holded regions in the 'confirmation' column he documented in memb	er's chart notes



TASIGNA

Affected Medications: TASIGNA (nilotinib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:		All medically-accepte		otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:		leukemia must be re	L, the Philadelphia ported.	ed. chromosome (Ph) status of the itive may receive authorization	YES / NO
Appropriate Treatment Regimen & Other Criteria:		For CML, new patien Tasigna.	t must have Ph-po	sitive CML for approval of	YES / NO
Exclusion Criteria:		New patients with che Philadelphia chromo: New patients with Cf	some (Ph)-negative	2.	YES / NO
Age Restriction:					N/A
Prescriber Restrictions:					N/A
Coverage Duration:		Approval = 12 month	ıs.		N/A
*Approvals require	tha	t all bolded regions in	the 'confirmation'	column be documented in mem	ber's chart notes.



TAZORAC

Affected Medications: TAZORAC (tazarotene)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ Psoriasis of fingernails or toenails.	
	□ Oral lichen planus.	
	☐ Congenital ichthyoses (X-linked recessive ichthyosis, non-	N== (N=
	erythrodermic autosomal recessive lamellar ichthyosis, autosomal	YES / NO
	dominant ichthyosis vulgaris).	
	□ Basal cell carcinoma.	
	☐ Mycosis fungoides lesions/cutaneous T-cell lymphomas.	
	☐ Keratosis pilaris (atrophicans).	
	☐ Treatment of other non-cosmetic conditions (eg, actinic keratoses, skin	
	neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic	
	acne, comedonal acne).	
Required Medical		N/A
Information:		
Appropriate	☐ Acne vulgaris after a trial with at least 1 other topical retinoid product	
Treatment	(eg, tretinoin cream/gel/solution/microgel, adapalene).	
Regimen &	☐ For the treatment of other non-cosmetic conditions (eg, actinic	VEC / NO
Other Criteria:	keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne	YES / NO
	rosacea, cystic acne, comedonal acne) exceptions can be made if the	
	patient has tried at least 1 other therapy.	
Exclusion	□ Cosmetic skin conditions (eg, alopecia, hyperpigmentation, liver spots,	
Criteria:	melasma/cholasma, seborrheic keratosis, stretch marks, scarring,	
	wrinkles, premature aging, photo-aged or photo-damaged skin,	
	mottled hyper- and hypopigmentation, benign facial lentigines,	YES / NO
	roughness, telangiectasia, skin laxity, keratinocytic atypia, melanocytic	11.5 / 110
	atypia, dermal elastosis).	
	□ Coverage not recommended for anything not listed under Covered	
	Uses.	
Age		N/A
Restriction:		14/71
Prescriber		N/A
Restrictions:		-
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
DUITATION		



POLICY NAME: TECFIDERA

Affected Medications: Tecfidera (dimethyl fumarate)

Effective Date: <u>08/01/2013</u> Last Review Date: <u>05/22/2012</u>

Medical Information:	 □ Diagnosis of a relapsing form of multiple sclerosis. □ CBC (within 6 months) before initiating treatment, then annually and 	
	as clinically indicated	YES / NO
Treatment Regimen &	 □ Initial dose of 120mg BID 7 days, then increasing to 240mg BID thereafter For use in MS □ Patient has failed interferon beta-1a or -1b (Avonex, Rebif, Betaseron or Extavia), or glatiramer acetate (Copaxone). □ Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Rebif, Betaseron or Extavia), or glatiramer acetate (Copaxone) can be made if the patient is unable to administer injections due to dexterity issues, visual impairment, depression or mood disorders. □ Patients who have tried natalizumab (Tysabri) for MS and have a relapsing form of MS will receive authorization, they are not required to try an interferon beta product or glatiramer acetate. 	YES / NO
Exclusion Criteria:	☐ Concurrent use of Avonex, Betaseron, Extavia, Rebif, Copaxone, Tysabri or Gilenya	YES / NO
Age Restriction:	☐ Age > 18 years	YES / NO
Prescriber Restrictions:	 Prescribed by or after consultation with a neurologist or an MS specialist. 	YES / NO
Coverage Duration:	☐ Approval = 12 months, unless otherwise noted.	YES / NO



POLICY NAME: THALOMID

Affected Medications: THALOMID (thalidomide)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D,	CONFIRMATION*
	☐ Myelofibrosis with myeloid metaplasia,	
	☐ Progressive solitary plasmacytoma or smoldering myeloma that has	
	progressed to active/symptomatic myeloma,	YES / NO
	□ Systemic light chain amyloidosis,	
	□ Waldenstrom's macroglobulinemia.	
Required	Erythema nodosum leprosum (ENL),	
Medical	☐ Thalomid is used for maintenance therapy or as part of a combination	
Information:	regimen in a patient with moderate to severe neuritis for acute	
	therapy.	
	Active/symptomatic myeloma or progressive solitary plasmacytoma,	
	☐ Thalomid is warranted in any of the following settings:	
	a) Thalomid is used in combination with dexamethasone or both	
	melphalan and prednisone as primary induction therapy,	
	b) Thalomid is used as maintenance monotherapy for patients	
	responding to primary induction therapy or for patients with stable or	
	responsive disease following stem cell transplant,	YES / NO
	c) Thalomid is used as salvage or palliative therapy.	
	☐ Use for treatment of myelofibrosis with myeloid metaplasia.	
	Systemic light chain amyloidosis,	
	☐ Thalomid is used as primary treatment in combination with	
	dexamethasone.	
	Waldenstrom's macroglobulinemia,	
	☐ Thalomid is used as monotherapy or in combination with rituximab.	
	☐ In females of childbearing potential, pregnancy is excluded as	
	confirmed by a negative serum or urine pregnancy test.	
Appropriate	☐ All patients are monitored for signs and symptoms of	
Treatment	thromboembolism.	
Regimen &	☐ Female patients of child-bearing potential and male patients are	YES / NO
Other Criteria:	instructed on the importance and proper utilization of appropriate	
	contraceptive methods for Thalomid use.	
Exclusion	□ Pregnancy.	YES / NO
Criteria:		125 / 140
Age		N/A
Restriction:		,



Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 12 months.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



POLICY NAME: TOBI PODHALER

Affected Medications: TOBI PODHALER ® (tobramycin inhalation powder), TOBI / tobramycin nebulized solution

when used as a Part B medication

Effective Date: 03/01/2014

Last Review Date: 12/11/2013

Part D: Yes (TOBI Podhaler only) Part B: Yes

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	□ When tobramyo	d indications not otherv in (TOBI) nebulized solu policy does not apply.	vise excluded from part D. tion is used as a part D	CONFIRMATION* YES / NO
Required Medical Information:	☐ Diagnosis of Cys	tic Fibrosis, phenotyping	not required	YES / NO
Appropriate Treatment Regimen & Other Criteria:	tobramycin or cl	inical rationale for avoid 28 day on / 28 day off u eatment of <i>Pseudomon</i> e		YES / NO
Exclusion Criteria:				N/A
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:	, ,	onths, unless otherwise		YES / NO
"Approvais require	unat an bolaea region	is in the confirmation o	olumn be documented in me	inder's chart notes.



POLICY NAME: TOPAMAX/ZONEGRAN

Affected Medications: TOPAMAX (Brand name), TOPAMAX SPRINKLE (Brand name), ZONEGRAN, ZONISAMIDE

Effective Date: <u>01/01/2014</u> Last Review Date: <u>06/12/2013</u>

Medical Information: Appropriate Treatment Regimen & Other Criteria: Exclusion Criteria: Weight loss treatment except if patient is being treated for seizures, bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, bipolar disorder, migraine headache, bulimia nervosa, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, etc who are using topiramate or zonisamide only for weight loss OR for patients who are using topiramate or zonisamide to prevent weight gain or produce weight loss caused by other medications such as antipsychotics [eg, clozapine, olanzapine, quetiapine, risperidone, thioridazine] or antidepressants). Smoking cessation therapy (exceptions are not recommended for patients with psychiatric conditions who are using topiramate or zonisamide only for smoking cessation OR patients who have successfully stopped smoking and are using topiramate or zonisamide to prevent relapse). Age Restriction: Prescriber Restrictions: Coverage Duration: Meight loss treatment except if patient is being treated for seizures, bipolar disorder, migraine neot recommended for patients who are using topiramate or zonisamide to prevent relapse). N/A Prescriber Restrictions: Approval = 12 months, unless otherwise specified. YES / NO	Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
commonly used to prevent migraines (beta blockers, depakote, TCAs) unless contraindicated. Weight loss treatment except if patient is being treated for seizures, bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, who are using topiramate or zonisamide t	Required Medical Information:		N/A
bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, etc who are using topiramate or zonisamide only for weight loss OR for patients who are using topiramate or zonisamide to prevent weight gain or produce weight loss caused by other medications such as antipsychotics [eg, clozapine, olanzapine, quetiapine, risperidone, thioridazine] or antidepressants). Smoking cessation therapy (exceptions are not recommended for patients with psychiatric conditions who are using topiramate or zonisamide only for smoking cessation OR patients who have successfully stopped smoking and are using topiramate or zonisamide to prevent relapse). Age	Appropriate Treatment Regimen & Other Criteria:	commonly used to prevent migraines (beta blockers, depakote, TCAs) unless contraindicated.	YES / NO
Restriction: Prescriber Restrictions: Coverage Duration: N/A N/A N/A N/A N/A N/A N/A N/	Exclusion Criteria:	bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, etc who are using topiramate or zonisamide only for weight loss OR for patients who are using topiramate or zonisamide to prevent weight gain or produce weight loss caused by other medications such as antipsychotics [eg, clozapine, olanzapine, quetiapine, risperidone, thioridazine] or antidepressants). Smoking cessation therapy (exceptions are not recommended for patients with psychiatric conditions who are using topiramate or zonisamide only for smoking cessation OR patients who have successfully stopped smoking and are using topiramate or zonisamide	YES / NO
Restriction: Prescriber Restrictions: Coverage Duration: Approval = 12 months, unless otherwise specified. YES / NO	Age		N/A
Restrictions: Coverage Duration: N/A Approval = 12 months, unless otherwise specified. YES / NO			,
Coverage Duration: Approval = 12 months, unless otherwise specified. YES / NO			N/A
Duration:		D. Accorded 42 worth and to other forces (find	N== / NO
	_	Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require that all bolded regions in the 'confirmation' column be documented in member's chart notes.		that all holded regions in the 'confirmation' column be documented in member	er's chart notes



TOPICAL RETINOID PRODUCTS

Affected Medications: ADAPALENE, ATRALIN, AVITA, DIFFERIN, EPIDUO, RETIN-A, RETIN-A MICRO, TRETINOIN,

TRETIN-X, VELTIN, ZIANA

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB: ID#:	Provider:	Dx:
Covered Uses:	 □ All FDA-approved indications not other □ For topical tretinoin products (example Retin-A Micro, Tretin-X, and generic top □ Actinic keratosis/treatment of precance □ Ichthyosis. □ Warts. □ Keloids. □ Lichen planus. □ Oral leukoplakia. □ Darier's disease (keratosis follicularis). □ Treatment of other non-cosmetic condicarcinoma [skin cancer], confluent and 	s include Atralin, Avita, Retin-A, pical tretinoin), erous skin lesions.	YES / NO
Required Medical Information:			N/A
Appropriate Treatment Regimen & Other Criteria:	Topical tretinoin products (examples included A Micro, Tretin-X, and generic topical tretin approval for the treatment of other nor dermatitis/eczema, folliculitis, milia, ke hyperplasia/cyst, basal cell carcinoma [sereticulated papillomatosis) can be made 1 other therapy. Topical adapalene products (examples included: and generic adapalene products), approval for the treatment of other nor dermatitis/eczema, folliculitis, milia, ke hyperplasia/cyst, basal cell carcinoma [sereticulated papillomatosis, Darier's disect can be made if the patient has tried at lace Coverage of the combination clindamy and the combination adapalene plus be (Epiduo) is recommended for acne vulgindications are not recommended.	oin), n-cosmetic conditions (eg, ratosis pilaris, sebaceous skin cancer], confluent and e if the patient has tried at least ude Differin gel, Differin cream, n-cosmetic conditions (eg, ratosis pilaris, sebaceous skin cancer], confluent and ease, molluscum contagiosum) east 1 other therapy. cin plus tretinoin product (Ziana)	YES / NO



Exclusion Criteria:	☐ Use in the treatment of cosmetic conditions (e.g., liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photoaged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation caused by folliculitis, acne, or eczema, melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis).	YES / NO
Age Restriction:		N/A
Prescriber		N/A
Restrictions:		•
Coverage	☐ Approval = 12 months, unless otherwise noted.	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in member	er's chart notes.



TRACLEER

Affected Medications: TRACLEER (Bosentan)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: No

Member:		DOB:	ID#:	Provider:	Dx:	
Covered Uses:		• •	n Letairis or Traclee	wise excluded from Part D. r for treatment of pulmonar		RMATION* 6 / NO
Required Medical Information:		<u>``</u>	upport NYHA Classi within normal limit	•	YES	6 / NO
Appropriate Treatment Regimen & Other Criteria:		diuretics, oxygen, d Documentation of t contraindicated) OF receptor antagonist	igoxin) - not require rial with at least 1 P I patient at high risk n Letairis or Traclee	is first-line (anticoagulants, d. DE5 inhibitor (unless necessitating endothelin r may continue therapy if the		6 / NO
Exclusion Criteria:		Evidence of liver dy	sfunction. Int administration o	re systolic dysfunction. f glyburide, cyclosporine,	YES	/ NO
Age Restriction:						N/A
Prescriber Restrictions:		Prescribed by or in o	consultation with a	cardiologist or a pulmonolog	ist. YES	6 / NO
Coverage Duration:		Approval = 12 mont	•	·		NO NO
*Approvals require	that	all bolded regions in	the 'confirmation'	column be documented in m	nember's chart	notes.



TRELSTAR

Affected Medications: TRELSTAR (triptorelin)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:	□ A	ll FDA-approved ir	dications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required	Prosta	ate cancer , must r	neet one of the follo	owing:	
Medical		ocally advanced, r	ecurrent or metasta	itic disease (including palliativ	e
Information:	tr	eatment) OR			
	ra	•	or clinically localized	nt ADT in combination with disease with intermediate or	YES / NO
	ра	•	e prostate to shrink	ion with brachytherapy in the prostate to an acceptable	
Appropriate					
Treatment					N/A
Regimen &					IN/ A
Other Criteria:					
Exclusion	□ U	se as neoadjuvant	ADT for radical pro	statectomy.	YES / NO
Criteria:					125 / 110
Age					N/A
Restriction:					N/A
Prescriber Restrictions:					N/A
Coverage Duration:	□ A	pproval = 12 mont	hs, unless otherwis	e specified.	YES / NO
*Approvals require	that all	l holded regions in	the 'confirmation'	column be documented in me	ember's chart notes.



TYSABRI

Affected Medications: TYSABRI (natalizumab)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Member:	 DOB:	ID#:	Provider:	Dx:
Covered Uses:	All FDA approved in	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:		sing form of MS. s disease (CD).	ve CD with evidence of protein).	YES / NO
Appropriate Treatment Regimen & Other Criteria:	response to, or is use following MS medicinterferon beta-1b or fingolimod (Gilen Exceptions to having (Avonex, Betaserong depression or a modern of these cases, the fingolimod (Gilenyal-1b.) In these cases, the fingolimod (Gilenyal-1b.) In the se cases, the fingolimod	sing form of MS and nable to tolerate, the cations: interferon be (Betaseron, Extavia) mya). Ing tried an interferon be code disorder. In patient should try go a), but is not require sease (CD). Intelled to severely active per cate of the atment with reaptopurine, or me gonists for CD for at lizumab pegol, or intelled to the TNF and criteria of treatment wed if steroids are conference of the conference	has had an inadequate erapy with at least two of the eta-1a (Avonex, Rebif), , glatiramer acetate (Copaxone) in beta-1a or -1b product can be made if the patient has atiramer acetate (Copaxone) or d to try an interferon beta-1a or over CD with evidence of protein) and has had an a corticosteroids (systemic), thotrexate, and patient has least 2 months each, fliximab, and had an inadequate antagonists. In the with corticosteroids contraindicated or not desired, or methotrexate must be tried in the corticosteroids.	YES / NO



i i	Concurrent use of another immunomodulator (eg, Rebif, Betaseron,	
Criteria:	Extavia, Copaxone or Avonex) or fingolimod (Gilenya) in multiple	
	sclerosis (MS) patients.	
	Use in MS patients with chronic progressive MS.	
	Concurrent use with immunosuppressants (eg, 6-mercaptopurine,	VEC / NO
	azathioprine, cyclosporine, methotrexate) or tumor necrosis factor	YES / NO
	(TNF) alfa inhibitors (eg, infliximab, adalimumab, certolizumab pegol)	
	in Crohn's disease (CD) patients.	
	Ulcerative colitis is a not covered indication.	
Age	Adults	YES / NO
Restriction:		
Prescriber	MS. Prescribed by a neurologist or an MS specialist registered with the	VEC / NO
Restrictions:	TOUCH prescribing program.	YES / NO
	CD. Prescribed by a physician registered with the TOUCH program.	
Coverage	Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		



VARIZIG

Affected Medications: VARIZIG (varicella zoster immune globulin (human) IM injection)

Effective Date: <u>09/01/2013</u>
Last Review Date: <u>08/14/2013</u>

Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
	☐ For postexposure prophylaxis of varicella in high-risk individuals	YES / NO
Required Medical Information:	Documentation of immunocompromised patient , defined as: □ newborns of mothers with varicella shortly before or after delivery, □ premature infants, neonates and infants younger than 1 year, □ adults without evidence of immunity, □ pregnant women	YES / NO
Appropriate Treatment Regimen & Other Criteria:	☐ If repeat dose necessary due to re-exposure > 3weeks after initial administration	YES / NO
Exclusion Criteria:	☐ Coagulation disorders	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 6 months	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in mem	ber's chart notes.



VENTAVIS

Drug Name: VENTAVIS (iloprost)
Effective Date: 10/14/2009
Last Review Date: 10/14/2009
Part D: No Part B: Yes

Covered Uses:	All FDA-approved indications not otherwise benefit design.	c excluded from from YES / NO
Required documentation:	Documentation of complete & current trea NYHA Functional Status: □ Class III OR □ Class IV Mean pulmonary artery pressure is: □ ≥ 25 mmHg at rest OR	tment course required. YES / NO
	□ ≥ 30 mmHg with exertion Acute Vasoreactivity testing must be comp □ Positive □ Negative	leted
Appropriate Treatment Regimen:	The following supportive care should be co Anticoagulants Diuretics Oxygen Digoxin Initial approval requires documented failur rationale for avoidance to the following: Calcium channel blockers Phosphodiesterase Inhibitors: Revall Prostacyclin derivatives (Letairis, Trong) High Risk Patient warrants treatme Subsequent approval requires documentat Defined by exercise endurance echocardiographic testing hemodynamic testing BNP, functional class	e, intolerance, or clinical YES / NO Itio, Adcirca Facleer, Thelin) Int with Prostacyclin
Exclusion Criteria:	Prior intolerance or allergic reaction to request. PAH secondary to pulmonary venous hyper or disorders of the respiratory system (eg. disease, OSA)	tension (left-sided disease)



Age	□ ≥ 18 years	YES / NO
Restriction:		
Provider	☐ Pulmonologist or Cardiologist	YES / NO
Restriction:		
Approval	☐ Initial approval = 6 months	YES / NO
Duration:	☐ Subsequent approval = 12 months	
*Approvals require t	hat all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



VICTRELIS

Affected Medications: VICTRELIS (boceprevir)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved in	ndications not otherv	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information: Appropriate Treatment Regimen & Other Criteria:	WNL, serum album or ascites), □ evidence of active lessesses □ HCV-RNA > 100IU/n WNL, serum album or ascites), evidence of active lesses les l	in ≥ 3.4, platelets Williver disease (elevate completed or will be alfa and ribavirin pries prescribed in combinalfa and ribavirin. The consistent with FDA comments at 12 weeks: The discontinue, The discontinue, The addl 12wks (total comments at 24 weeks:	completing a 4-week lead-in or to initiating boceprevir and nation as triple-drug therapy Approved Response Guided	YES / NO
Exclusion Criteria:	chronic HCV and hurecurrent hepatitis monotherapy, in per who have failed the inhibitor for HCV (expanded in Males whose females).	uman immune deficience of after liver (or othe ediatric patients (age erapy with bocepreviet, telaprevir). or may become pregular partners are pregnate medications that ar		YES / NO



Age	□ Adults	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Initial Approval = 8wks (TW12).	YES / NO
Duration:	☐ Initial Approval = 44wk, if pt has cirrhosis.	
*Approvals require	that all bolded regions in the 'confirmation' column be documented in members	er's chart notes.



VIMIZIM

Affected Medications: VIMIZIM (elosulfase alfa)

Effective Date: <u>07/09/2014</u>
Last Review Date: <u>07/09/2014</u>
Part D: No Part B: Yes (J3490)

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved in	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ The diagnosis was (confirmed by an enzy	me assay or DNA testing.	YES / NO
Appropriate Treatment Regimen & Other Criteria:	, ,	_	reaction, there will be ailable when administered	YES / NO
Exclusion Criteria:				N/A
Age Restriction:	☐ 5 years old or great	ter		YES / NO
Prescriber Restrictions:	☐ Geneticist			YES / NO
Coverage Duration:		ths, unless otherwise	•	YES / NO
*Approvals require	that all bolded regions in	n the 'confirmation'	column be documented in m	ember's chart notes.



VPRIV

Affected Medications: VPRIV (velaglucerase alfa)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	YES / NO
Required	☐ Patient has a diagnosis of type 1 Gaucher disease.	
Medical	☐ Diagnosis of Gaucher disease is confirmed by an enzyme assay	
Information:	demonstrating a deficiency of beta-glucocerebrosidase enzyme activity.	YES / NO
	☐ Therapy is initiated for a patient with one or more of the following	
	conditions: anemia, thrombocytopenia, bone disease, hepatomegaly,	
	or splenomegaly.	
Appropriate		
Treatment		N/A
Regimen &		IV/A
Other Criteria:		
Exclusion	☐ Concomitant therapy with miglustat	YES / NO
Criteria:		125 / 110
Age		N/A
Restriction:		14/74
Prescriber		N/A
Restrictions:		IV/A
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
Duration:		
*Approvals require	that all holded regions in the 'confirmation' column be documented in memb	er's chart notes.



XALKORI

Affected Medications: XALKORI (crizotinib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	Dx:
Covered Uses:		All FDA-approved	indications not other	wise excluded from Part D.	CONFIRMATION*
		Plus, patients with	n non-small cell lung o	cancer (NSCLC) already started	
		on crizotinib.			YES / NO
Required		For the FDA-appro	oved indication of NS	CLC for patients new to therapy	,
Medical		ALK status require	ed.		YES / NO
Information:		·			ILS / NO
Appropriate					
Treatment		NSCLC, patient ne	w to therapy must be	ALK-positive for approval.	VEC / NO
Regimen &		, i	1,		YES / NO
Other Criteria:					
Exclusion		Patients with anal	olastic lymphoma kina	ase (ALK)-negative NSCLC not	
Criteria:		already started or	r crizotonib.		V/50 / NO
		Patients with NSC	LC initiating therapy v	whose ALK status is unknown.	YES / NO
			3 17		
Age					N/A
Restriction:					IN/A
Prescriber		Prescribed by or a	fter consultation with	n an oncologist	YES / NO
Restrictions:					
Coverage		Approval will be for	or 12 months, unless	otherwise specified.	YES / NO
Duration:					·
*Approvals require	that	t all bolded regions	in the 'confirmation'	column be documented in mer	nber's chart notes.



XELJANZ

Affected Medications: XELJANZ (Tofacitinib)

Effective Date: <u>06/01/2013</u> Last Review Date: <u>06/10/2013</u>

Covered Uses:	red Uses: All FDA-approved indications not otherwise excluded from Part D.		
Required Medical Information:		Documented latent TB screening with either a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) with a negative result Glomerular filtration rate > 40 ml/min. Complete set of the following laboratory tests: CBC (WBC, Hgb, Hct, Platlets), LFTs (AST / ALT), BMP (SCr)	YES / NO
Appropriate	Rhe	eumatoid arthritis (RA)	
Treatment Regimen &		pt tried at least 2 oral DMARDs for ≥ 12wks (hydroxychloroquine, leflunomide, sulfasalazine, minocycline, methotrexate) AND	
Other Criteria:		pt has documented failure, intolerance or clinical rationale for avoidance to TWO of the following: Adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade), golimumab (Simponi) or cetolizumab pegol (Cimzia).	N/A
Exclusion Criteria:		Concurrent use with immunosuppresant medications other than methotrexate or corticosteroids.	
		Patients with a history of diverticulitis, myelodysplastic syndromes, unresolved cytopenias, or active or progressive liver, kidney or hematologic disease. Evidence of active, latent or inadequately treated TB, herpes zoster.	N/A
Age		RA: age > 18 years.	N/A
Restriction:			IN/A
Prescriber Restrictions:		Prescribed by or in consultation with a Rheumatologist	N/A
Coverage Duration:		Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that	all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



XENAZINE

Affected Medications: XENAZINE (tetrabenazine)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ Tardive dyskinesia	(TD). e and related tic disore	ise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:				N/A
Appropriate Treatment Regimen & Other Criteria:				N/A
Exclusion Criteria:	☐ Coverage is not rec Covered Uses.	commended for circum	istances not listed in the	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:	Tourette syndrome hemiballism, presc	ribed by or after consulust be prescribed by c	Huntington's disease, rs, hyperkinetic dystonia, or Iltation with a neurologist. or after consultation with a	YES / NO
Coverage Duration:		ths, unless otherwise		YES / NO
*Approvals require	that all bolded regions is	n the 'confirmation' co	olumn be documented in mei	mber's chart notes.



XEOMIN

Affected Medications: XEOMIN (IncobotulinumtoxinA)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: No Part B: Yes

Covered Uses:		All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		Additional indications will be evaluated by a pharmacist and/or a	
		physician on a case-by-case basis.	YES / NO
Required		Documentation of product to be used, sites to be injected and the	
Medical		dosage used in the injections.	YES / NO
Information:			
Appropriate		For all covered uses other than focal dystonia, hemifacial spasm,	
Treatment		orofacial dyskinesia, blepharospasm, severe writer's cramp, layngeal	
Regimen &		spasm and dysphonia, it should be established that the patient is	
Other Criteria:		unresponsive to conventional treatments (medication, physical therapy or other widely accepted treatment).	
		When available, FDA approved products will be preferred over non-	
		FDA approved products.	YES / NO
		Coverage may be continued unless any two treatments in a row fail to	
		produce a satisfactory clinical response.	
		If two subsequent treatments do not produce satisfactory response,	
		one trial authorization of an alternative botulinum toxin may be	
		authorized.	
Exclusion		Use in the management of cosmetic uses (eg, facial rhytides, frown	
Criteria:		lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face	
		and neck rejuvenation, platsymal bands, rejuvenation of the peri-	
		orbital region), allergic rhinitis, gait freezing in Parkinsons disease,	
		vaginismus, dysphagia (upper esophageal sphincter dysfunction),	YES / NO
		interstitial cystitis, Crocodile tears syndrome, tension headaches,	
		myofascial pain, irritable colon, biliary dyskinesia, other forms of	
		smooth muscle spasm not specifically addressed in this policy, lower	
		limb spasticity or fibromyalgia.	
Age			N/A
Restriction:			IN/A
Prescriber		Chronic migraine only if prescribed by or after consultation with, a	YES / NO
Restrictions:		neurologist or HA specialist.	
Coverage		All indications approval except strabismus: 4 treatments/12 months.	YES / NO
Duration:		Stabismus approval: 6 treatments/12 months.	-
*Approvals require	that	all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



XGEVA

Affected Medications: XGEVA (denosumab)

Effective Date: 01/01/2014
Last Review Date: 08/14/2013
Part D: Yes Part B: Yes

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved in	ndications not other	vise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Documentation of □ Patient has giant ce □ Documentation that likely to result in se 	complete current tre ell tumor of the bone at tumor is unresecta	ble or that surgical resection is	
Appropriate Treatment Regimen & Other Criteria:	Initial approval require rationale for avoidance Zometa (zoledronic Recent oral exam to Evidence of concur Subsequent approval reference For treatment of Giant	e to the following: c acid), Aredia (pame o assess osteonecros rent treatment with equires documentati Cell Tumor of Bone:	•	YES / NO
Exclusion Criteria:	☐ Hypocalcemia.	r allergic reaction to	requested medication. t of osteonecrosis of the jaw.	YES / NO
Age Restriction:				N/A
Prescriber Restrictions:				N/A
Coverage Duration:	☐ Initial approval = 6 ☐ Subsequent approv	vals = 12 months		YES / NO
*Approvals require	that all holded regions is	n the 'confirmation'	column be documented in men	nber's chart notes.



XIFAXAN

Affected Medications: XIFAXAN (rifaximin)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:		Dx:
Covered Uses:	□ Tr			wise excluded from Pa cile infection in select	art D.	CONFIRMATION* YES / NO
Required Medical Information:						N/A
Appropriate Treatment Regimen & Other Criteria:	m		·	ve failed 1 course of ncomycin for coverage	e to be	YES / NO
Exclusion Criteria:		_	ne recommended d ention of hepatic e	ose of two 550 mg tab nchepalopathy.	lets daily	YES / NO
Age Restriction:	□ ≥:	12 years				YES / NO
Prescriber Restrictions:						N/A
Coverage Duration:	□ Ot		proval = 1 month c			YES / NO
*Approvals require	that all	bolded regions in	the 'confirmation'	column be documente	ed in membe	er's chart notes.



XOFIGO

Affected Medications: XOFIGO (radium 223)

Effective Date: 09/01/2013 Last Review Date: 07/10/2013 Part D: No Part B: Yes

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION*
		YES / NO
Required	☐ Diagnosis of castration-resistant prostate cancer (CRPC), symptomatic	
Medical	bone metastases, and no known visceral metastatic disease	
Information:		YES / NO
	 Documentation of progression of bone metastases post docetaxel therapy or docetaxel-ineligible. 	TES / NO
Appropriate	☐ For Baseline CBC	
Treatment	$\Box ANC \ge 1.5 \times 10^9 / L$	
Regimen &	□ Platelet count $\ge 100 \times 10^9$ /L	YES / NO
Other Criteria:	☐ Hemoglobin ≥ 10 g/dL	
Exclusion	☐ Concomitant chemotherapy	
Criteria:		YES / NO
Age	□ ≥ 18 years	YES / NO
Restriction:		
Prescriber		N/A
Restrictions:		IN/A
Coverage	☐ Approval = 6 months	YES / NO
Duration:		
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



XOLAIR

Affected Medications: XOLAIR (omalizumab)

Effective Date: 01/01/2014
Last Review Date: 09/23/2012
Part D: Yes Part B: Yes

Member:	DOB:	ID#:	Provider:	Dx:
Covered Uses:	☐ All FDA-approved i	ndications not other	wise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	of at least 30 IU/m Asthma, patient has a pose allergen-specific perennial aeroallergens (group aeroallergens) Seasonal or perennial patient has position spores, house duritro testing (i.e., a one or more relevire.)	L. itive skin test or in vitage antibodies such allergens (eg, house dureathers, mold spores ass, pollen, weeds). allergic rhinitis (SAR we skin testing (eg, grant standard andeathers) allerging the blood test for allerging it with the skin testing (eg, grant standard andeathers).	rass, tree, or weed pollen, mold er, cockroach) and/or positive in en-specific IgE antibodies) for ass, tree, or weed pollen, mold	YES / NO
Appropriate Treatment Regimen & Other Criteria:	adequately control inhaled corticoster alternative, if LABA contrainding sustained-release to montelukast), AND inadequate control requirement for sy exacerbation(s), or increasing need (exacerbation) induced asthma). Seasonal or perennial must meet the following alternative,	ria: patient's asthma lled by concomitant usoid and a long-acting cated or pt has intoles; heophylline or a leuk lead of the lead of the latest of the lates	a day) for short-acting inhaled preventative use for exercise-	YES / NO



*Approvals require	that all bolded regions in the 'confirmation' column be documented in membe	er's chart notes.
Duration:		
Coverage	☐ Approval = 12 months, unless otherwise specified.	YES / NO
	immunologist, or gastroenterologist.	
	☐ EG/EE/EC, if prescribed by or in consultation with an aller gist,	
	☐ SAR/PAR if prescribed by an allergist, immunologist, or pulmonologist.	TES / NO
Restrictions:	consultation with an allergist, immunologist, or pulmonologist.	YES / NO
Prescriber	☐ Moderate to severe persistent asthma if prescribed by, or in	
	omalizumab.	
Restriction:	☐ Asthma patients aged 6 to 12 years, if already started and stabilized on	TES / NO
Age	□ Patients > 12 years	YES / NO
Criteria:		163 / 110
Exclusion	☐ For the treatment of atopic dermatitis.	YES / NO
	corticosteroid.	
	□ patient has tried therapy with a systemic or orally administered topical	
	Eosinophilic colitis (EC)	
	Eosinophilic gastroenteritis (EG), Eosinophilic esophagitisi (EE),	
	the patient's immediate environment (eg, work, home).	
	☐ for pts with allergies to animals, these animals must be removed from	
	receiving immunotherapy, AND	
	□ pt has had immunotherapy, is receiving immunotherapy, or will be	
	3 of these classes during one allergy season AND	
	corticosteroid, or montelukast or pt has tried at least one drug from all	
	or low-sedating anthistamine/nasal antihistamine, a nasal	



XYREM

Affected Medications: XYREM (sodium oxybate)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Patient has a diagnosis of narcolepsy and experiences episodes of cataplexy OR Patient has a diagnosis of narcolepsy and experiences excessive daytime sleepiness with symptoms that limit the ability to perform normal daily activities. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 □ If the patient has received prior treatment with Xyrem, □ the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. 	YES / NO
Exclusion Criteria:	☐ If the patient is taking alcohol (ethanol), sedative/hypnotic drugs, or other CNS depressants.	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 3 months	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



POLICY NAME: ZELBORAF

Affected Medications: ZELBORAF (vemurafenib)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Member:		DOB:	ID#:	Provider:	_ Dx:
	1				
Covered Uses:		All FDA-approved	indications not other	wise excluded from Part D.	CONFIRMATION*
		Patients with mela	anoma already starte	d on vemurafenib.	YES / NO
		Malignancies not	specified in Exclusior	Criteria.	
Required		FDA-approved ind	ication of melanoma	, for patients new to therapy,	
Medical		BRAFV600E status	required.		YES / NO
Information:			•		ILS / NO
Appropriate					
Treatment		Melanoma, patier	nt new to therapy mu	st have BRAFV600E mutation for	YES / NO
Regimen &		approval.			TES / NO
Other Criteria:					
Exclusion		Patients with mela	anoma with wild-type	BRAF (ie, no detected	
Criteria:		BRAFV600E mutat	tion) not already star	ted on vemurafenib.	
		Patients with mela	anoma initiating ther	apy with vemurafenib whose	YES / NO
		BRAFV600E status	is unknown.		
Age					N/A
Restriction:					IN/A
Prescriber		Prescribed by or a	fter consultation wit	h an oncologist	YES / NO
Restrictions:					
Coverage		Approval = 12 mo	nths, unless otherwis	e specified.	YES / NO
Duration:					
*Approvals require	that	all bolded regions	in the 'confirmation'	column be documented in memb	er's chart notes.



ZORBTIVE

Affected Medications: ZORBTIVE (somatropin)

Effective Date: <u>01/01/2014</u> Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	☐ Diagnosis of short bowel syndrome (SBS).	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Patients must be receiving specialized nutritional support (e.g., TPN, IPN, PPN, rehydration solutions, electrolyte replacement, high complex-carbohydrate, low-fat diet) in conjunction with optimal management of SBS. For patients who have received at least 4 weeks of Zorbtive therapy, 	YES / NO
	must show decrease in specialized nutritional support requirement as measured by total volume, total calories or infusion frequency and stabilized or increased in weight.	
Exclusion Criteria:	 Active malignancy (newly diagnosed or recurrent). Acute critical illness due to complications following open heart or abdominal surgery, accidental trauma or acute respiratory failure. 	YES / NO
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Initial approval: 4 weeks.☐ Renewal: Up to maximum 8 weeks	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	er's chart notes.



ZYKADIA

Affected Medications: ZYKADIA (ceritinib)

Effective Date: <u>07/01/2014</u>
Last Review Date: <u>06/11/2014</u>
Part D: No Part B: Yes (J9999)

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 □ Documentation of ALK status □ Documentation of progression on crizotinib therapy □ Karnofsky Performance Status OR ECOG performance status 	YES / NO
Appropriate Treatment Regimen & Other Criteria:	 Documentation of planned monthly monitoring of liver function tests, and dose adjustment as needed Regularly scheduled Qtc monitoring with concomitant diagnosis of CHF, bradyarrhythmias, electrolyte abnormalities, or medications that prolong Qtc interval Additional authorization requires documentation of positive response to therapy 	YES / NO
Exclusion Criteria:		N/A
Age Restriction:	□ 18 years of age and older	YES / NO
Prescriber Restrictions:	□ Oncologist	YES / NO
Coverage Duration:	☐ Approval = 6 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in memb	per's chart notes.



ZYTIGA

Affected Medications: ZYTIGA (abiraterone)

Effective Date: <u>01/01/2014</u>
Last Review Date: <u>09/23/2012</u>

Covered Uses:	☐ All FDA-approved indications not otherwise excluded from Part D.	CONFIRMATION* YES / NO
Required Medical Information:	 Patient must have metastatic, castration-resistant prostate cancer. Patient must have tried and failed a docetaxel-containing chemotherapy regimen. Zytiga will be used in combination with prednisone. 	YES / NO
Appropriate Treatment Regimen & Other Criteria:		N/A
Exclusion Criteria:		N/A
Age Restriction:		N/A
Prescriber Restrictions:		N/A
Coverage Duration:	☐ Approval = 12 months, unless otherwise specified.	YES / NO
*Approvals require	that all bolded regions in the 'confirmation' column be documented in members.	per's chart notes.