UnitedHealthcare®

April 2019

medical policy update bulletin

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, Utilization Review Guideline, and Quality of Care Guideline updates.*

***Where information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.**

Overview

This bulletin provides complete details on UnitedHealthcare Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline (CDG), Utilization Review Guideline (URG), and/or Quality of Care Guideline (QOCG) updates. The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, CDGs, URGs, and QOCGs is available at **UHCprovider.com** > *Policies and Protocols > Commercial Policies > Medical & Drug Policies and Coverage Determination Guidelines.*

Tips for using the Medical Policy Update Bulletin:

- From the table of contents, click the policy title to be directed to the corresponding policy update summary.
- From the policy updates table, click the policy title to view a complete copy of a new, updated, or revised policy.

Policy Update Classifications

New

New clinical coverage criteria and/or documentation review requirements have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria or documentation review requirements; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria and/or documentation review requirements

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare®

Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

In This Issue

Medical Policy Updates

Page

NEW

UPDATED

REVISED

Medical Benefit Drug Policy Updates

UPDATED

REVISED

In This Issue

Coverage Determination Guideline (CDG) Updates

UPDATED

Utilization Review Guideline (URG) Updates

REVISED

Medical Policy Updates

Policy Title	Effective Date	Coverage Rationale
NEW		

Preimplantation Genetic Testing	Jun. 1, 2019	**Preimplantation Genetic Testing (PGT) for Monogenic/single gene defects (PGT-M) or inherited structural chromosome rearrangements (PGT-SR) is proven and medically necessary using polymerase chain reaction (PCR), next generation sequencing (e.g., Chromosomal Rearrangements), or chromosomal microarray (e.g., IdentifySGD, HumanKaryoMap) for the following**:
		• The embryo is at increased risk of a recognized inherited disorder due to one of the following:
		  ○ The parents are carriers of an autosomal recessive disease
		  ○ At least one parent is a carrier of an autosomal dominant, sex-linked, or mitochondrial condition
		  ○ At least one parent is a carrier of a balanced structural chromosome rearrangement
		• Human leukocyte antigen (HLA) typing on an embryo in order for the future child to provide bone marrow or blood to treat an affected sibling
		
		Preimplantation Genetic Testing (PGT) is unproven and not medically necessary for all other populations and conditions due to insufficient evidence of efficacy.
		This includes but is not limited to PGT using chromosome microarray (e.g., Spectrum PGS, Spectrum-PGD+PGS), PCR, or next generation sequencing (e.g., NexCCS) for the following:
		• Aneuploidy screening (PGT-A)
		• Determining gender when the embryo is not at risk for a sex linked disorder

Policy Title	**Effective Date**	**Summary of Changes**
UPDATED		

Bone or Soft Tissue Healing and Fusion Enhancement Products	Apr. 1, 2019	• Updated list of related policies; added reference link to the policy titled *Platelet Derived Growth Factors for Treatment of Wounds*
		• Updated coverage rationale; replaced reference to "patients" with "individuals"
		• Updated definitions:
		  ○ Added definition of "RhBMP–7/ OP–1™ Putty"
		  ○ Modified definition of:
		  ▪ Amniotic Tissue Membrane
		  ▪ Bone Morphogenetic Proteins (BMP) and Recombinant Human Bone Morphogenetic Proteins (rhBMP)
		  ▪ Carrier Systems
		  ▪ Cell-Based Products
		  ▪ Ceramic-Based Products
		  ▪ Concentrated Bone Marrow Aspirate (CBMA)
		  ▪ Infuse™ Bone Graft
		  ▪ OptiMesh Grafting System®
		  ▪ Platelet-Rich Plasma
		• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

Cochlear Implants	Apr. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, FDA information, and references; no change to coverage rationale or lists of applicable codes

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Computerized Dynamic Posturography	Apr. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Apr. 1, 2019	• Updated list of related policies; added reference link to the policy titled *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements* • Updated list of applicable HCPCS codes; added notation to indicate the following are the only FES devices verified by the Centers for Medicare & Medicaid Services (CMS) Pricing, Data Analysis, and Coding (PDAC) to be reported with HCPCS code E0770: ○ WalkAide (Innovative Neurotronics) ○ Odstock ODFS Pace FES System (Odstock Medical/Boston Brace) ○ NESS L300 and H200 devices (Bioness) • Updated supporting information to reflect the most current description of services and references
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Apr. 1, 2019	• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes
Gastrointestinal Motility Disorders, Diagnosis and Treatment	May 1, 2019	• Updated coverage rationale: ○ Replaced language indicating "defecography is proven and medically necessary for *treating* intractable constipation or constipation in members who have one or more of the [listed] conditions that are suspected to be the cause of impaired defecation" with "*conventional* defecography is proven and medically necessary for *evaluating* intractable constipation or constipation in members who have one or more of the [listed] conditions that are suspected to be the cause of impaired defecation" ○ Added language to clarify *conventional* defecography is unproven and not medically necessary for evaluating all other conditions not [listed as proven and medically necessary] • Updated list of applicable CPT codes; removed 95980, 95981, and 95982 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references
Intrauterine Fetal Surgery	May 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Updated coverage rationale; replaced language indicating "intrauterine fetal surgery (IUFS) is unproven and not medically necessary for treating the conditions [listed in the policy]" with "intrauterine fetal surgery (IUFS) is unproven and not medically necessary for treating *all other* conditions*, including but not limited to* [the conditions listed in the policy]" • Updated list of applicable CPT codes: ○ Removed 59070 ○ Revised description for 59897 • Updated supporting information to reflect the most current clinical evidence and references

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Apr. 1, 2019	**Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be implemented on **Apr. 1, 2019**.
		• Updated coverage rationale:
		  ○ Replaced language indicating "the use of one of the [listed] gene expression tests *listed [in the policy]* is proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with non-metastatic breast cancer when *all of the [listed]* criteria are met" with "the use of one of the [listed] gene expression tests is *considered* proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with non-metastatic breast cancer when criteria are met *as summarized [in the policy]*"
		  ○ Modified language to clarify services are unproven and not medically necessary (as described) *due to insufficient evidence of efficacy*
		• Updated list of applicable CPT codes:
		  ○ Added 0013U, 0014U, and 0069U
		  ○ Revised description for 0011M *(quarterly code edit)*

Occipital Neuralgia and Headache Treatment	Apr. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes
Thermography	Apr. 1, 2019	• Updated supporting information to reflect the most current description of services, clinical evidence, and references; no change to coverage rationale or list of applicable codes

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Chromosome Microarray Testing (Non-Oncology Conditions)	Jun. 1, 2019	• Updated list of related policies; added reference link to the policy titled *Preimplantation Genetic Testing*
		• Revised coverage rationale:
		  ○ Simplified content
		  ○ Added language to indicate:
		  ▪ Genome-wide comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is
			Genome-wide comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis is proven and medically necessary for the following:
			• Evaluation of an embryo/fetus in the following cases:
			  ○ Women undergoing invasive prenatal testing (i.e., amniocentesis, chorionic villus sampling or fetal tissue sampling)
			  ○ Testing the products of conception following pregnancy loss
			  ○ Intrauterine Fetal Demise or Stillbirth
			• Evaluation of individuals with one or more of the following:
			  ○ Multiple anomalies not specific to a well-delineated genetic syndrome and cannot be identified by a clinical evaluation alone
			  ○ Non-syndromic Developmental Delay/Intellectual Disability
			  ○ Autism spectrum disorder
			  ○ Isolated severe congenital heart disease

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions) *(continued)*	Jun. 1, 2019	proven and medically necessary for evaluation of: - An embryo/fetus for testing the products of conception following pregnancy loss - Individuals with isolated severe congenital heart disease - A biological parent of a fetus or child with an equivocal chromosome microarray result ▪ Genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis for preimplantation genetic testing (PGT) is addressed in the policy titled *Preimplantation Genetic Testing* ○ Removed language pertaining to genome-wide comparative genomic hybridization microarray testing or single nucleotide polymorphism (SNP) chromosomal microarray analysis for preimplantation genetic testing (PGT) in embryos; refer to the policy titled Preimplantation	• Evaluation of biological parent of a fetus or child with an equivocal chromosome microarray result **Genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis is unproven and not medically necessary for all other populations and conditions due to insufficient evidence of efficacy.** This includes but is not limited to: • Epilepsy **Note**: Genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray analysis for the following are addressed in other Medical Policies: • The evaluation of cancer is addressed in the Medical Policy titled Molecular Oncology Testing for Cancer Diagnosis Prognosis, and Treatment Decisions. • Preimplantation genetic testing (PGT) is addressed in the Medical Policy titled Preimplantation Genetic Testing.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Chromosome Microarray Testing (Non-Oncology Conditions) *(continued)*	Jun. 1, 2019	Genetic Testing • Removed definition of "Preimplantation Genetic Testing (PGT)" • Updated list of applicable ICD-10 diagnosis codes; added N96, 026.0, 026.1, 026.2, 026.3, Q20.8, Q20.9, Q21.8, Q21.9, Q24.0, Q24.1, Q24.2, Q24.3, Q24.4, Q24.5, Q24.6, Q24.8, Q24.9, and Z87.74 • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	
Fecal Calprotectin Testing	Apr. 7, 2019	• Revised coverage rationale: ○ Simplified content ○ Added language to indicate fecal measurement of calprotectin is proven and medically necessary for establishing the diagnosis or for management of Crohn's disease and ulcerative colitis ○ Replaced language indicating "fecal measurement of calprotectin is unproven and not medically necessary for the diagnosis *and* management of *all* conditions *including but not limited to [those listed in the policy]*" with "fecal measurement of calprotectin is unproven and not medically necessary for *establishing* the diagnosis *or for* management of *any*	**Fecal measurement of calprotectin is proven and medically necessary for establishing the diagnosis or for management of the following**: • Crohn's Disease • Ulcerative Colitis **Due to insufficient evidence of efficacy, fecal measurement of calprotectin is unproven and not medically necessary for establishing the diagnosis or for management of any other condition**.

Medical Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Fecal Calprotectin Testing *(continued)*	Apr. 7, 2019	*other* condition *[not listed as proven and medically necessary]"* • Added list of applicable ICD-10 diagnosis codes: K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.914, K51.918, K51.919, K58.0, K58.9, K59.1, and R19.7 • Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Apr. 1, 2019	• Updated list of applicable HCPCS codes to reflect quarterly code edits; added C9141
Infliximab (Remicade®, Inflectra™, Renflexis™)	Apr. 1, 2019	• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or lists of applicable codes
Ketamine	Apr. 1, 2019	• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes
Self-Administered Medications List	Apr. 1, 2019	• Updated list of applicable HCPCS codes to reflect quarterly code edits; added C9040
Trogarzo™ (Ibalizumab-Uiyk)	Apr. 1, 2019	• Updated supporting information to reflect the most current references; no change to coverage rationale or lists of applicable codes

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion	Apr. 1, 2019	• Revised coverage rationale; updated coverage criteria for: **Polyarticular Juvenile Idiopathic Arthritis** ***Initial Therapy*** ○ Replaced criterion requiring "Actemra is *initiated and titrated* according to FDA labeled dosing" with "Actemra is *dosed* according to FDA labeled dosing" ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Actemra; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of	Please refer to the Oncology Medication Clinical Coverage Policy for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers only to Actemra (tocilizumab) injection for intravenous infusion for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, & cytokine release syndrome. Actemra, for self-administered subcutaneous injection, is obtained under the pharmacy benefit and is indicated in the treatment of rheumatoid arthritis and giant cell arteritis. **Actemra is proven and medically necessary for the treatment of:** I. **Polyarticular juvenile idiopathic arthritis when ALL of the following criteria are met:** A. For **initial therapy, all** of the following: 1. Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA); **and** 2. Actemra is dosed according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule):

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	positive clinical response to Actemra; and ▪ Actemra is dosed according to US Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): - 10mg/kg every 4 weeks for patients weighing < 30kg - 8mg/kg every 4 weeks for patients weighing ≥ 30kg and ▪ Patient is not receiving Actemra in combination with either of the following: - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] **Rheumatoid Arthritis**	a. 10mg/kg every 4 weeks for patients weighing < 30kg b. 8mg/kg every 4 weeks for patients weighing ≥ 30kg **and** 3. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response to Actemra; **and** 2. Actemra is dosed according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 10mg/kg every 4 weeks for patients weighing < 30kg b. 8mg/kg every 4 weeks for patients weighing ≥ 30kg **and** 3. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] II. **Rheumatoid arthritis when ALL of the following criteria are met:** A. For **initial therapy, all** of the following: 1. Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and** 2. History of failure, contraindication, or intolerance to at least **one** non-biologic DMARD [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, minocycline, etc.]; **and** 3. Actemra is dosed according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of 800mg every 4 weeks (or equivalent dose and interval schedule); **and** 4. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	***Initial Therapy*** ○ Replaced criterion requiring "Actemra is *initiated and titrated* according to FDA labeled dosing" with "Actemra is *dosed* according to FDA labeled dosing" ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Actemra; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response; and ▪ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis up to a maximum of 800mg every 4 weeks (or equivalent dose and interval schedule); and ▪ Patient is not receiving Actemra in combination with either of the following: - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] - Janus kinase inhibitor [e.g.,	(adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response; **and** 2. Actemra is dosed according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of 800mg every 4 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] III. **Systemic juvenile idiopathic arthritis when ALL of the following criteria are met**: A. For **initial therapy, all** of the following: 1. Diagnosis of systemic juvenile idiopathic arthritis (SJIA); **and** 2. Actemra is dosed according to US Food and Drug Administration labeled dosing for systemic juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 12mg/kg every 2 weeks for patients weighing < 30kg b. 8mg/kg every 2 weeks for patients weighing ≥ 30kg **and** 3. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response; **and** 2. Actemra is dosed according to US Food and Drug Administration labeled dosing for systemic juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 12mg/kg every 2 weeks for patients weighing < 30kg b. 8mg/kg every 2 weeks for patients weighing ≥ 30kg **and**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	Xeljanz (tofacitinib), Olumiant (baricitinib)] **Systemic Juvenile Idiopathic Arthritis** ***Initial Therapy*** ○ Replaced criterion requiring "Actemra is *initiated and titrated* according to FDA labeled dosing" with "Actemra is *dosed* according to FDA labeled dosing" ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Actemra; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response; and ▪ Actemra is dosed according to FDA labeled dosing for systemic juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): - 12mg/kg every 2 weeks for patients weighing < 30kg - 8mg/kg every 2 weeks for patients weighing ≥ 30kg and ▪ Patient is not receiving Actemra in combination	3. Patient is **not** receiving Actemra in combination with either of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] IV. **Cytokine Release Syndrome when ALL of the following criteria are met**: A. For **initial therapy, all** of the following: 1. Diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS); **and** 2. Actemra is prescribed according to US Food and Drug Administration labeled dosing for CRS: a. 12mg/kg for patients weighing < 30kg b. 8mg/kg for patients weighing ≥ 30kg; up to a maximum of 800mg per infusion **and** 3. Actemra is prescribed for a maximum of 4 doses B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response; **and** 2. Actemra is prescribed according to US Food and Drug Administration labeled dosing for CRS: a. 12mg/kg for patients weighing < 30kg b. 8mg/kg for patients weighing ≥ 30kg; up to a maximum of 800mg per infusion **and** 3. Actemra is prescribed for a maximum of 4 doses

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	with either of the following: - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] **Cytokine Release Syndrome (CRS)** ***Initial Therapy*** ○ Replaced criterion requiring "Actemra is *prescribed* according to FDA labeled dosing" with "Actemra is *dosed* according to FDA labeled dosing" ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response; and ▪ Actemra is dosed according to FDA labeled dosing for CRS: - 12mg/kg for patients weighing < 30kg - 8mg/kg for patients weighing ≥ 30kg; up to a maximum of 800mg per infusion and	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Actemra® (Tocilizumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	▪ Actemra is prescribed for a maximum of 4 doses • Updated supporting information to reflect the most current CMS information and references	
Denosumab (Prolia® & Xgeva®)	Apr. 1, 2019	• Revised coverage rationale; added language to indicate: ○ Xgeva is proven for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases ○ Xgeva is medically necessary for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases when all of the following criteria are met: ▪ Diagnosis of castration-resistant prostate cancer; and ▪ Presence of metastatic disease; and ▪ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ▪ Xgeva dosing is in accordance with the	Refer to the policy for complete details on the coverage guidelines for Denosumab (Prolia® & Xgeva®).

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Denosumab (Prolia® & Xgeva®) *(continued)*	Apr. 1, 2019	United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ▪ Authorization is for no more than 12 months ○ For patients currently on Xgeva for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases, continued use will be approved based on the following criteria: ▪ Provider attests to a positive clinical response; and ▪ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ▪ Authorization is for no more than 12 months ○ Xgeva is proven for osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates ○ Xgeva is medically necessary for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Denosumab (Prolia® & Xgeva®) *(continued)*	Apr. 1, 2019	not responding to bisphosphonates when all of the following criteria are met: ▪ Diagnosis of systemic mastocytosis; and ▪ Patient has bone pain ▪ Diagnosis of osteoporosis or osteopenia based on one of the following: - BMD T-score ≤-1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or - History of one of the following resulting from minimal trauma: • Vertebral compression fracture • Fracture of the hip • Fracture of the distal radius • Fracture of the pelvis • Fracture of the proximal humerus and ▪ Refractory (within the past 30 days), contraindication	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Denosumab (Prolia® & Xgeva®) *(continued)*	Apr. 1, 2019	(including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ▪ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ▪ Authorization for no more than 12 months ○ For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, continued use will be approved based on the following criteria: ▪ Provider attests to a positive clinical response; and ▪ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ▪ Authorization is for no more than 12 months • Updated list of applicable ICD-10 diagnosis codes for Xgeva;	

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Denosumab (Prolia® & Xgeva®) *(continued)*	Apr. 1, 2019	added C61 and D47.02 • Updated supporting information to reflect the most current CMS information and references	
Ocrevus™ (Ocrelizumab)	Apr. 1, 2019	• Updated list of related policies; removed reference link to the policy titled *Oncology Medication Clinical Coverage* • Revised coverage rationale: ○ Removed reference link to the policy titled *Oncology Medication Clinical Coverage* for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications ○ Added language to indicate: ▪ Initial therapy authorization is for no more than 6 months ▪ Continuation of therapy authorization is for no more than 12 months ○ Updated coverage criteria for relapsing forms of multiple sclerosis; removed criterion requiring patient has history of failure following a trial for at least 4 weeks or history of intolerance or contraindication to one of the following: ▪ Interferon β-1a (Avonex®, Rebif®, Plegridy™) ▪ Interferon β-1b	**Ocrevus (ocrelizumab) is proven for:** I. **Primary Progressive Multiple Sclerosis** **Ocrevus is medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when ALL of the following criteria are met:** A. Diagnosis of primary progressive multiple sclerosis (PPMS); **and** B. **One** of the following: 1. **Initial therapy for ocrelizumab** when meeting **both** of the following: a. Patient is **not** receiving ocrelizumab in combination with **any** of the following: i. Disease modifying therapy (e.g., interferon beta preparations, daclizumab, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) ii. B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) iii. Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** b. Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; **and** c. Initial authorization is for no more than 6 months **or** 2. **Continuation therapy for ocrelizumab** when meeting **all** of the following: a. Patient has previously received treatment with ocrelizumab; **and** b. Documentation of positive clinical response to ocrelizumab therapy; **and** c. Patient is **not** receiving ocrelizumab in combination with **any** of the following: i. Disease modifying therapy (e.g., interferon beta preparations, daclizumab, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, or teriflunomide)

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ocrevus™ (Ocrelizumab) *(continued)*	Apr. 1, 2019	(Betaseron® or Extavia®) ▪ Glatiramer acetate (Copaxone®, Glatopa®) ▪ Dimethyl fumarate (Tecfidera®) ▪ Teriflunomide (Aubagio®) ▪ Fingolimod (Gilenya®) ▪ Alemtuzumab (Lemtrada®) ▪ Natalizumab (Tysabri®) • Updated supporting information to reflect the most current references	ii. B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) iii. Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** d. Continued dosing: One 600 mg intravenous dose every 6 months; **and** e. Authorization is for no more than 12 months II. **Relapsing Forms of Multiple Sclerosis** **Ocrevus is medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when BOTH of the following criteria are met:** A. Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); **and** B. **One** of the following: 1. **Initial therapy for ocrelizumab** meeting all of the following: a. Patient is **not** receiving ocrelizumab in combination with **any** of the following: i. Disease modifying therapy (e.g., interferon beta preparations, daclizumab, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) ii. B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) iii. Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** b. Initial dosing: One time 300 mg intravenous course of doses on days 1 and 15; **and** c. Initial authorization is for no more than 6 months **or** 2. **Continuation therapy for ocrelizumab** when meeting **all** of the following: a. Patient has previously received treatment with ocrelizumab; **and** b. Documentation of positive clinical response to ocrelizumab therapy; **and** c. Patient is **not** receiving ocrelizumab in combination with **any**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Ocrevus™ (Ocrelizumab) *(continued)*	Apr. 1, 2019		of the following: i. Disease modifying therapy (e.g., interferon beta preparations, daclizumab, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, or teriflunomide) ii. B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab) iii. Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) **and** d. Continued dosing: One 600 mg intravenous dose every 6 months; **and** e. Authorization is for no more than 12 months **Ocrevus is unproven and not medically necessary for the treatment of:** • Lupus nephritis • Rheumatoid arthritis • Systemic lupus erythematosus
Orencia® (Abatacept) Injection for Intravenous Infusion	Apr. 1, 2019	• Revised coverage rationale; updated coverage criteria for: **Polyarticular Juvenile Idiopathic Arthritis** ***Initial Therapy*** ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Orencia; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response; and ▪ Orencia is dosed according to US Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or	This policy refers to Orencia (abatacept) injection for intravenous infusion. **Orencia is proven and medically necessary for the treatment of:** I. **Polyarticular juvenile idiopathic arthritis when all of the following criteria are met:** A. For **initial therapy, all** of the following: 1. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); **and** 2. Orencia is initiated and titrated according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 10mg/kg every 4 weeks for patients weighing <75kg b. 1,000mg every 4 weeks for patients weighing ≥75kg **and** 3. Patient is not receiving Orencia in combination with **either** of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	equivalent dose and interval schedule): - 10mg/kg every 4 weeks for patients weighing <75kg - 1,000mg every 4 weeks for patients weighing ≥75kg and ▪ Patient is not receiving Orencia in combination with either of the following: - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] **Rheumatoid Arthritis** ***Initial Therapy*** ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Orencia; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of	B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response; **and** 2. Orencia is dosed according to US Food and Drug Administration labeled dosing for polyarticular juvenile idiopathic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 10mg/kg every 4 weeks for patients weighing <75kg b. 1,000mg every 4 weeks for patients weighing ≥75kg **and** 3. Patient is not receiving Orencia in combination with **either** of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] II. **Rheumatoid arthritis** when **all** of the following criteria are met: A. For **initial therapy, all** of the following: 1. Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and** 2. Orencia is initiated and titrated according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule): a. 500mg every 4 weeks for patients weighing <60kg b. 750mg every 4 weeks for patients weighing 60kg to 100kg c. 1,000mg every 4 weeks for patients weighing >100kg **and** 3. Patient is not receiving Orencia in combination with **either** of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] B. For **continuation of therapy**, **all** of the following: 1. Documentation of positive clinical response; **and** 2. Orencia is dosed according to US Food and Drug Administration labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule): a. 500mg every 4 weeks for patients weighing <60kg b. 750mg every 4 weeks for patients weighing 60kg to 100kg

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	positive clinical response; and ▪ Orencia is dosed according to FDA labeled dosing for rheumatoid arthritis up to a maximum of (or equivalent dose and interval schedule): - 500mg every 4 weeks for patients weighing <60kg - 750mg every 4 weeks for patients weighing 60kg to 100kg - 1,000mg every 4 weeks for patients weighing >100kg and ▪ Patient is not receiving Orencia in combination with either of the following: - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] **Psoriatic Arthritis** ***Initial Therapy***	c. 1,000mg every 4 weeks for patients weighing >100kg **and** 3. Patient is not receiving Orencia in combination with **either** of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] III. **Psoriatic arthritis** when **all** of the following criteria are met: A. For **initial therapy, all** of the following: 1. Diagnosis of active psoriatic arthritis (PsA); **and** 2. Orencia is initiated and titrated according to US Food and Drug Administration labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 500mg every 4 weeks for patients weighing <60kg b. 750mg every 4 weeks for patients weighing 60kg to 100kg c. 1,000mg every 4 weeks for patients weighing >100kg **and** 3. Patient is not receiving Orencia in combination with **any** of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] B. For **continuation of therapy**, **all** of the following: 1. Documentation of a positive clinical response; **and** 2. Orencia is dosed according to US Food and Drug Administration labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule): a. 500mg every 4 weeks for patients weighing <60kg b. 750mg every 4 weeks for patients weighing 60kg to 100kg c. 1,000mg every 4 weeks for patients weighing >100kg **and** 3. Patient is not receiving Orencia in combination with **any** of the following: a. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	○ Modified list of janus kinase inhibitors the patient must not receive in combination with Orencia; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of a positive clinical response; and ▪ Orencia is dosed according to US Food and Drug Administration labeled dosing for psoriatic arthritis up to a maximum of (or equivalent dose and interval schedule): - 500mg every 4 weeks for patients weighing <60kg - 750mg every 4 weeks for patients weighing 60kg to 100kg - 1,000mg every 4 weeks for patients weighing >100kg and ▪ Patient is not receiving Orencia in combination with any of the following: - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab),	b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]. **Orencia is unproven and not medically necessary for the treatment of:** • Multiple sclerosis • Systemic lupus erythematosus • Graft versus host disease (GVHD) • Uveitis associated with Behçet's disease

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Orencia® (Abatacept) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	Simponi (golimumab)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] • Updated supporting information to reflect the most current clinical evidence, CMS information, and references	
Rituximab (Rituxan® & Truxima®)	Apr. 1, 2019	• Changed policy title; previously titled *Rituxan® (Rituximab)* • Revised coverage rationale: ○ Updated list of applicable drug products; added Truxima® (rituximab-abbs) ○ Added language to indicate: ▪ "Rituximab" will be used to refer to both Rituxan and Truxima; replaced references to "Rituxan" with "rituximab" in coverage statements ▪ Rituximab is proven and medically necessary for the treatment of immunotherapy-related encephalitis when all of the following criteria are met: - Diagnosis of immunotherapy-related encephalitis; and	This policy refers only to the following drug products, rituximab injections for intravenous infusion: • Rituxan® (rituximab) • Truxima® (rituximab-abbs) "Rituximab" will be used to refer to both Rituxan and Truxima. For oncology indications and for Rituxan Hycela (rituximab/hyaluronidase human), please refer to the Oncology Medication Clinical Coverage Policy for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). **Rituximab is proven for the treatment of:** I. **Immune thrombocytopenic purpura (ITP)** *Additional information to support medical necessity review where applicable:* **Rituximab is medically necessary for the treatment of immune thrombocytopenic purpura when all of the following criteria are met:** A. Diagnosis of immune thrombocytopenic purpura (ITP); **and** B. Documented platelet count < 50 x 10^9 / L; **and** C. History of failure, contraindication, or intolerance to **one** of the following: 1. Anti-D immunoglobulin

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Rituximab (Rituxan® & Truxima®) *(continued)*	Apr. 1, 2019	- Recent immunotherapy treatment with a checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)]; and - One of the following: • Patient has had limited or no improvement after treatment with glucocorticoids for a minimum of 7 days; or • History of contraindication or intolerance to glucocorticoids; or • Both of the following: ○ Patient is positive for autoimmune encephalopathy antibody; and ○ Infectious causes (e.g., viral) of encephalitis have been ruled out ○ Added example of an autoimmune mucocutaneous	2. Corticosteroids 3. Immune globulin 4. Splenectomy II. **Autoimmune mucocutaneous blistering diseases (e.g. pemphigus vulgaris)** III. **Rituximab is proven and medically necessary for the treatment of Wegener's granulomatosis or microscopic polyangiitis (both ANCA-associated vasculidities) when both of the following criteria are met**: A. Diagnosis of Wegener's granulomatosis or microscopic polyangiitis; **and** B. **One** of the following: 1. Patient is receiving concurrent therapy with glucocorticoids 2. History of contraindication or intolerance to glucocorticoids IV. **Autoimmune hemolytic anemia, including chronic cold agglutinin disease** V. **Rituximab is proven and medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met**: A. Moderate to severe disease activity [e.g., swollen, tender joints with limited range of motion]; **and** B. **One** of the following: 1. Patient is receiving concurrent therapy with methotrexate 2. History of contraindication or intolerance to methotrexate **and** C. History of failure, contraindication or intolerance to at least **one** tumor necrosis factor (TNF) inhibitors [e.g., adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)]; **and** D. Patient is not receiving rituximab in combination with **either** of the following: 1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] VI. **Post-transplant B-lymphoproliferative disorder** VII. **Neuromyelitis optica** VIII. **Rituximab is proven and medically necessary for the treatment**

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Rituximab (Rituxan® & Truxima®) *(continued)*	Apr. 1, 2019	blistering disease: pemphigus vulgaris • Updated list of applicable ICD-10 diagnosis codes; added G04.81, G97.82, T45.1X5A, T45.1X5D, T45.1X5S, and Z92.22 • Updated supporting information to reflect the most current background information, FDA and CMS information, and references	**of immunotherapy-related encephalitis when all of the following criteria are met:** A. Diagnosis of immunotherapy-related encephalitis; **and** B. Recent immunotherapy treatment with a checkpoint inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)]; **and** C. **One** of the following: 1. Patient has had limited or no improvement after treatment with glucocorticoids for a minimum of 7 days; **or** 2. History of contraindication or intolerance to glucocorticoids; **or** 3. **Both** of the following: a. Patient is positive for autoimmune encephalopathy antibody; **and** b. Infectious causes (e.g., viral) of encephalitis have been ruled out **Rituximab is unproven and not medically necessary for the treatment of:** • Anti-GM1 antibody-related neuropathies • Kaposi sarcoma-associated herpes virus-related multicentric Castleman disease • Pure red cell aplasia • Systemic lupus erythematosus • Acquired factor VIII inhibitors • Polyneuropathy associated with anti-MAG antibodies • Idiopathic membranous nephropathy • Chronic graft-versus-host disease • Reduction of anti-HLA antibodies in patients awaiting renal transplant • Multiple sclerosis • Dermatomyositis and polymyositis While a beneficial effect of rituximab has been reported in some of these conditions, none of them have shown positive results in large, controlled clinical trials.
Simponi Aria® (Golimumab) Injection for Intravenous Infusion	Apr. 1, 2019	• Revised coverage rationale; updated coverage criteria for: **Ankylosing Spondylitis** ***Initial Therapy*** ○ Changed US Food and Drug	This policy refers only to Simponi Aria (golimumab) injection for intravenous infusion for the treatment of ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis. Simponi, for self-administered subcutaneous injection, is obtained under the pharmacy benefit and is indicated in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Simponi Aria® (Golimumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	Administration (FDA) labeled maximum dosing recommendation from "2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" to "*2 mg/kg at weeks 0 and 4 upon initiation of therapy, then* 2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response to Simponi Aria; and ▪ Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and ▪ Patient is not receiving Simponi Aria in combination with either of the following: - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] - Janus kinase	**Simponi Aria is proven and/or medically necessary for the treatment of:** I. **Ankylosing spondylitis when all of the following criteria are met**: A. For **initial therapy, all** of the following: 1. Diagnosis of active ankylosing spondylitis (AS); **and** 2. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis, up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Simponi Aria in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] B. For **continuation therapy**, **all** of the following: 1. Documentation of positive clinical response to Simponi Aria; **and** 2. Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Simponi Aria in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] II. **Psoriatic arthritis when all of the following criteria are met**: A. For **initial therapy, all** of the following: 1. Diagnosis of active psoriatic arthritis (PsA); **and** 2. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis, up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Simponi Aria in combination with any of the following: a. Biologic disease-modifying antirheumatic drug (DMARD)

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Simponi Aria® (Golimumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	inhibitor [e.g., Xeljanz (tofacitinib)] **Psoriatic Arthritis** ***Initial Therapy*** ○ Changed FDA labeled maximum dosing recommendation from "2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" to "*2 mg/kg at weeks 0 and 4 upon initiation of therapy, then* 2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response to Simponi Aria; and ▪ Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); and ▪ Patient is not receiving Simponi Aria in combination with any of the following: - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab),	[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] B. For **continuation therapy, all** of the following: 1. Documentation of positive clinical response to Simponi Aria; **and** 2. Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Simponi Aria in combination with any of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] III. **Rheumatoid arthritis when all of the following criteria are met**: A. For **initial therapy, all** of the following: 1. Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and** 2. **One** of the following: a. Patient is receiving concurrent therapy with methotrexate b. History of contraindication or intolerance to methotrexate; **and** 3. Simponi Aria is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis up to a maximum of 2 mg/kg at weeks 0 and 4 upon initiation of therapy, then 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 4. Patient is **not** receiving Simponi Aria in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] B. For **continuation therapy**, **all** of the following:

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Simponi Aria® (Golimumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	Cimzia (certolizumab), Orencia (abatacept)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]5 - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **Rheumatoid Arthritis** ***Initial Therapy*** ○ Changed FDA labeled maximum dosing recommendation ~~of~~ from "2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" to "*2 mg/kg at weeks 0 and 4 upon initiation of therapy, then* 2 mg/kg every 8 weeks (or equivalent dose and interval schedule)" ○ Modified list of janus kinase inhibitors the patient must not receive in combination with Simponi Aria; added Olumiant (baricitinib) ***Continuation of Therapy*** ○ Added criteria requiring: ▪ Documentation of positive clinical response to Simponi Aria; and ▪ Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg	1. Documentation of positive clinical response to Simponi Aria; **and** 2. Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing up to a maximum of 2 mg/kg every 8 weeks (or equivalent dose and interval schedule); **and** 3. Patient is **not** receiving Simponi Aria in combination with either of the following: a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Simponi Aria® (Golimumab) Injection for Intravenous Infusion *(continued)*	Apr. 1, 2019	every 8 weeks (or equivalent dose and interval schedule); and ▪ Patient is not receiving Simponi Aria in combination with either of the following: - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)] - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] • Updated supporting information to reflect the most current CMS information and references	
Stelara® (Ustekinumab)	Apr. 1, 2019	• Revised coverage rationale; updated coverage criteria for treatment of: ○ **Crohn's disease**; removed references to brand name products (Remicade/Inflectra) for infliximab ○ **Plaque psoriasis**; removed criterion requiring patient is a candidate for phototherapy • Updated supporting information to reflect the most current CMS information and references	This policy refers to Stelara (ustekinumab) injection. **Stelara is proven and medically necessary for the treatment of:** I. **Crohn's disease** when **all** of the following criteria are met: A. Diagnosis of moderately to severely active Crohn's disease; **and** B. **One** of the following: 1. History of failure, contraindication, or intolerance to at least **one** tumor necrosis factor (TNF) blocker [e.g., infliximab, Humira (adalimumab), Cimzia (certolizumab)]; **or** 2. **Both** of the following: a. History of failure, contraindication, or intolerance to at least **one** immunomodulator or corticosteroid (e.g., corticosteroids, 6-mercaptopurine, azathioprine, methotrexate, etc.)

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Stelara® (Ustekinumab) *(continued)*	Apr. 1, 2019		b. Patient has never failed a TNF blocker [e.g., infliximab, Humira (adalimumab), Cimzia (certolizumab)] **and** C. **One** of the following: 1. **Initial Therapy** a. Stelara is to be administered as an intravenous induction dose; **and** b. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease: i. 260mg for patients weighing ≤55kg ii. 390mg for patients weighing >55kg to ≤85kg iii. 520mg for patients weighing >85kg **and** c. Patient is not receiving Stelara in combination with **any** of the following: i. Biologic DMARD [e.g., infliximab, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **and** d. Authorization will be for one induction dose **or** 2. **Continuation Therapy** a. Patient is unable to self-administer subcutaneous doses; **and** b. Stelara is to be subcutaneously administered 8 weeks after the initial intravenous dose; **and** c. Stelara continuation dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease: 90mg every 8 weeks subcutaneously; **and** d. Patient is not receiving Stelara in combination with **any** of the following: i. Biologic DMARD [e.g., infliximab, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

Medical Benefit Drug Policy Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			
Stelara® (Ustekinumab) *(continued)*	Apr. 1, 2019		II. **Plaque psoriasis when all of the following criteria are met:** A. Diagnosis of moderate to severe plaque psoriasis; **and** B. Patient is a candidate for systemic therapy; **and** C. Patient is unable to self-administer subcutaneous doses; **and** D. Stelara is initiated and titrated according to US Food and Drug Administration labeled dosing for plaque psoriasis up to a maximum of (or equivalent dose and interval schedule): 1. 45mg every 12 weeks for patients weighing ≤100kg subcutaneously 2. 90mg every 12 weeks for patients weighing >100kg subcutaneously **and** E. Patient is not receiving Stelara in combination with **any** of the following: 1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] III. **Psoriatic arthritis when all of the following criteria are met:** A. Diagnosis of psoriatic arthritis; **and** B. Stelara is initiated and titrated according to US Food and Drug Administration labeled dosing for psoriatic arthritis up to a maximum of 90mg every 12 weeks subcutaneously (or equivalent dose and interval schedule); **and** C. Patient is unable to self-administer subcutaneous doses; **and** D. Patient is not receiving Stelara in combination with **any** of the following: 1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)] 3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] **Stelara is unproven and not medically necessary for the treatment of multiple sclerosis.** In available studies, Stelara does not demonstrate efficacy in the treatment of multiple sclerosis.

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		

Breast Reconstruction Post Mastectomy	May 1, 2019	• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Updated coverage rationale:
		  ○ Simplified content
		  ○ Replaced language indicating "in accordance with *Federal and State mandates*, the [listed] services are covered" with "in accordance with the *Women's Health and Cancer Rights Act of 1998*, the [listed] services are covered"
		  ○ Added language to clarify:
		  ▪ Removal, replacement or revision of an implant may be considered reconstructive in certain circumstances
		  ▪ UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to [those listed in the policy]
		  ▪ Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures; the fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure
		• Updated definition of:
		  ○ Cosmetic Procedures (California only)
		  ○ Mastectomy
		  ○ Reconstructive Procedures (California only)
		• Updated list of applicable ICD-10 diagnosis codes; added D48.61, D48.62, N65.0, and N65.1
		• Updated supporting information to reflect the most current references

Breast Repair/ Reconstruction Not Following Mastectomy	May 1, 2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section
		• Updated coverage rationale:
		  ○ Simplified content
		  ○ Added language to clarify:
		  ▪ Correction of inverted nipples is considered reconstructive when the member meets *the Women's Health and Cancer Rights Act (WHCRA)* criteria (see the policy titled *Breast Reconstruction Post Mastectomy* for details)
		  ▪ The breast reconstruction benefit does not include coverage for any of the following:
		  - Aspirations
		  - Biopsy (open or core)
		  - Excision of cysts
		  - Fibroadenomas or other benign or malignant tumors
		  - Aberrant breast tissue
		  - Duct lesions
		  - Nipple or areolar lesions

Coverage Determination Guideline (CDG) Updates

Policy Title	Effective Date	Summary of Changes
UPDATED		
Breast Repair/ Reconstruction Not Following Mastectomy *(continued)*	May 1, 2019	- Treatment of gynecomastia ▪ Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures; the fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure • Updated definitions: o Added definition of "Women's Health and Cancer Rights Act of 1998, §713(a)" o Removed definition of "Congenital Anomaly (California only)" o Modified definition of: ▪ Cosmetic Procedures (California only) ▪ Reconstructive Procedures (California only) • Updated supporting information to reflect the most current references
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/ Replacements	Apr. 1, 2019	• Reorganized policy template (no change to guidelines): o Simplified and relocated *Instructions for Use* o Removed Benefit Considerations section
Pectus Deformity Repair	Apr. 1, 2019	• Reorganized policy template: o Simplified and relocated *Instructions for Use* o Removed *Benefit Considerations* section • Updated coverage rationale: o Simplified content o Added language to clarify surgical repair of Pectus Carinatum *may be* considered reconstructive and medically necessary o Modified language pertaining to procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function to clarify the fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a Reconstructive Procedure • Updated definitions: o Removed definition of "Congenital Anomaly (California only)" o Modified definition of: ▪ Cosmetic Procedures (California only) ▪ Pectus Carinatum ▪ Reconstructive Procedures (California only)

Utilization Review Guideline (URG) Updates

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
REVISED			

Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Care	Apr. 1, 2019	**Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be implemented on **Apr. 1, 2019**.
		• Reorganized policy template:
		  ○ Simplified and relocated *Instructions for Use*
		  ○ Removed *Benefit Considerations* section
		• Revised coverage rationale; modified medical necessity criteria for an advanced radiologic imaging procedure in the hospital outpatient department:
		  ○ Changed age criterion from "less than ***10*** years of age" to "less than ***19*** years of age"
		• Updated list of applicable CPT codes; added 77046 and 77047
			An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary for individuals who meet ANY of the following criteria:
			• Less than 19 years of age
			• Require obstetrical observation
			• Require perinatology services
			• Have a known contrast allergy
			• Have a known chronic disease with prior radiology imaging procedures for the diagnosis, management or surveillance of the disease at the hospital outpatient department
			• Have pre-procedure imaging where the surgery or procedure is being performed at the hospital
			An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary when there are no geographically accessible appropriate alternative sites for the individual to undergo the procedure, including but not limited to the following:
			• Moderate or deep sedation or general anesthesia is required for the procedure; or
			• The equipment for the size of the individual is not available; or
			• Open magnetic resonance imaging is required because the member has a documented diagnosis of claustrophobia and/or severe anxiety
			An advanced radiologic imaging procedure in the hospital outpatient department is considered medically necessary when imaging in a physician's office or freestanding imaging center would reasonably be expected to delay care and adversely impact health outcome.
			All other advanced radiologic imaging procedures in the hospital outpatient department are considered not medically necessary.