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

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.

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.

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.

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.
### Medical Policy Updates

**NEW**
- Preimplantation Genetic Testing – Effective Jun. 1, 2019

**UPDATED**
- Bone or Soft Tissue Healing and Fusion Enhancement Products – Effective Apr. 1, 2019
- Cochlear Implants – Effective Apr. 1, 2019
- Computerized Dynamic Posturography – Effective Apr. 1, 2019
- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation – Effective Apr. 1, 2019
- Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome – Effective Apr. 1, 2019
- Gastrointestinal Motility Disorders, Diagnosis and Treatment – Effective May 1, 2019
- Intrauterine Fetal Surgery – Effective Apr. 1, 2019
- Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions – Effective Apr. 1, 2019
- Occipital Neuralgia and Headache Treatment – Effective Apr. 1, 2019
- Thermography – Effective Apr. 1, 2019

**REVISED**
- Chromosome Microarray Testing (Non-Oncology Conditions) – Effective Jun. 1, 2019
- Fecal Calprotectin Testing – Effective Apr. 7, 2019

### Medical Benefit Drug Policy Updates

**UPDATED**
- Clotting Factors, Coagulant Blood Products & Other Hemostatics – Effective Apr. 1, 2019
- Infliximab (Remicade®, Inflectra™, Renflexis™) – Effective Apr. 1, 2019
- Ketamine – Effective Apr. 1, 2019
- Self-Administered Medications List – Effective Apr. 1, 2019
- Trogarzo™ (Ibalizumab-Utok) – Effective Apr. 1, 2019

**REVISED**
- Actemra® (Tocilizumab) Injection for Intravenous Infusion – Effective Apr. 1, 2019
- Denosumab (Prolia® & Xgeva®) – Effective Apr. 1, 2019
- Ocrevus™ (Ocrelizumab) – Effective Apr. 1, 2019
- Orenzia® (Abatacept) Injection for Intravenous Infusion – Effective Apr. 1, 2019
- Rituximab (Rituxan® & Truxima®) – Effective Apr. 1, 2019
- Simponi Aria® (Golimumab) Injection for Intravenous Infusion – Effective Apr. 1, 2019
Medical Policy, Medical Benefit Drug Policy & Coverage Determination Guideline Updates

**In This Issue**

- Stelara® (Ustekinumab) – Effective Apr. 1, 2019

**Coverage Determination Guideline (CDG) Updates**

**UPDATED**
- Breast Reconstruction Post Mastectomy – Effective May 1, 2019
- Breast Repair/Reconstruction Not Following Mastectomy – Effective May 1, 2019
- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements – Effective Apr. 1, 2019
- Pectus Deformity Repair – Effective Apr. 1, 2019

**Utilization Review Guideline (URG) Updates**

**REVISED**
- Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Care – Effective Apr. 1, 2019
## Medical Policy Updates

### Preimplantation Genetic Testing

**Policy Title:** 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

**Policy Title:** 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

### Bone or Soft Tissue Healing and Fusion Enhancement Products

**Policy Title:** Updated list of related policies; added reference link to the policy titled *Platelet Derived Growth Factors for Treatment of Wounds*

**Policy Title:** Updated coverage rationale; replaced reference to “patients” with “individuals”

**Policy Title:** 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

**Policy Title:** Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references

### Cochlear Implants

**Policy Title:** 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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UPDATED</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Computerized Dynamic Posturography</td>
<td>Apr. 1, 2019</td>
<td>• Updated supporting information to reflect the most current clinical evidence, CMS information, and references; no change to coverage rationale or list of applicable codes</td>
</tr>
</tbody>
</table>
| 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:  
    o WalkAide (Innovative Neurotronics)  
    o Odstock ODFS Pace FES System (Odstock Medical/Boston Brace)  
    o 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:  
    o 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”  
    o 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:  
    o Removed 59070  
    o Revised description for 59897  
  • Updated supporting information to reflect the most current clinical evidence and references |
### Medical Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UPDATED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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. | 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 |
| 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 |                                                                                  |

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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 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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| *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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chromosome Microarray Testing (Non-Oncology Conditions) (continued)</td>
<td>Jun. 1, 2019</td>
<td><strong>Genetic Testing</strong>&lt;br&gt;• Removed definition of “Preimplantation Genetic Testing (PGT)”&lt;br&gt;• 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&lt;br&gt;• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references</td>
<td></td>
</tr>
<tr>
<td>Fecal Calprotectin Testing</td>
<td>Apr. 7, 2019</td>
<td>• Revised coverage rationale:&lt;br&gt;  o Simplified content&lt;br&gt;  o 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&lt;br&gt;  o 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 other condition.”</td>
<td><strong>Fecal measurement of calprotectin is proven and medically necessary for establishing the diagnosis or for management of the following:</strong>&lt;br&gt;  • Crohn’s Disease&lt;br&gt;  • Ulcerative Colitis&lt;br&gt;<strong>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.</strong></td>
</tr>
</tbody>
</table>
### Medical Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fecal Calprotectin Testing</td>
<td>Apr. 7, 2019</td>
<td><em>other condition [not listed as proven and medically necessary]</em></td>
</tr>
<tr>
<td><em>(continued)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Added list of applicable ICD-10 diagnosis codes: K50.00,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.211, K51.212,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K51.318, K51.319, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K51.912, K51.914, K51.918, K51.919, K58.0, K58.9, K59.1, and R19.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Updated supporting information to reflect the most current description of</td>
</tr>
<tr>
<td></td>
<td></td>
<td>services, clinical evidence, CMS information, and references</td>
</tr>
</tbody>
</table>
### 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-Uixk) | Apr. 1, 2019 | • Updated supporting information to reflect the most current references; no change to coverage rationale or lists of applicable codes

**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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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)] | a. 10mg/kg every 4 weeks for patients weighing < 30kg  
b. 8mg/kg every 4 weeks for patients weighing ≥ 30kg  
3. Patient is **not** receiving Actemra in combination with either of the following:  
   a. Biologic disease-modifying anti-rheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]  
   b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] |

<table>
<thead>
<tr>
<th>Rheumatoid Arthritis</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 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-biological 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 Policy Update Bulletin: April 2019**
Actemra®
(Tocilizumab)
Injection for Intravenous Infusion
(continued)

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVISED</td>
<td>Apr. 1, 2019</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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., 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)]

**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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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  
  - 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)]  
| | | | 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  
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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Actemra®</strong> <em>(Tocilizumab)</em> Injection for Intravenous Infusion <em>(continued)</em></td>
<td>Apr. 1, 2019</td>
<td>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)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cytokine Release Syndrome (CRS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Initial Therapy</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Replaced criterion requiring &quot;Actemra is prescribed according to FDA labeled dosing&quot; with &quot;Actemra is dosed according to FDA labeled dosing&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Continuation of Therapy</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Added criteria requiring:  - Documentation of positive clinical response; and  - Actemra is dosed according to FDA labeled dosing for CRS:  - 12mg/kg for patients weighing &lt; 30kg  - 8mg/kg for patients weighing ≥ 30kg; up to a maximum of 800mg per infusion and</td>
<td></td>
</tr>
</tbody>
</table>
## Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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:  
  o Xgeva is proven for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases  
  o 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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
</table>
| **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 |
<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td><strong>Denosumab (Prolia® &amp; Xgeva®) (continued)</strong></td>
<td></td>
</tr>
</tbody>
</table>
|                                                 | 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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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; |
<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denosumab (Prolia® &amp; Xgeva®) (continued)</td>
<td>Apr. 1, 2019</td>
<td>added C61 and D47.02 • Updated supporting information to reflect the most current CMS information and references</td>
<td></td>
</tr>
<tr>
<td>Ocrevus™ (Ocrelizumab)</td>
<td>Apr. 1, 2019</td>
<td>• Updated list of related policies; removed reference link to the policy titled Oncology Medication Clinical Coverage • Revised coverage rationale: o Removed reference link to the policy titled Oncology Medication Clinical Coverage for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs &amp; Biologics Compendium® (NCCN Compendium®) for oncology indications o 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 o 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</td>
<td>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)</td>
</tr>
</tbody>
</table>
## Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **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  

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**

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Ocrevus™ (Ocrelizumab) (continued)                | Apr. 1, 2019   | 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   | o 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

#### Orencia® (Abatacept) Injection for Intravenous Infusion (continued)

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td>Apr. 1, 2019</td>
<td>equivalent dose and interval schedule):</td>
<td>B. For <strong>continuation of therapy, all</strong> of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 10mg/kg every 4 weeks for patients weighing &lt;75kg</td>
<td>1. Documentation of positive clinical response; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 1,000mg every 4 weeks for patients weighing ≥75kg and</td>
<td>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):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Patient is not receiving Orencia in combination with either of the following:</td>
<td>a. 10mg/kg every 4 weeks for patients weighing &lt;75kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]</td>
<td>b. 1,000mg every 4 weeks for patients weighing ≥75kg and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]</td>
<td>3. Patient is not receiving Orencia in combination with <strong>either</strong> of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]</td>
</tr>
</tbody>
</table>

**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
   c. 1,000mg every 4 weeks for patients weighing >100kg

---

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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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 | 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:**  
1. **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 10⁹ / L; and  
    C. History of failure, contraindication, or intolerance to one of the following:  
       1. Anti-D immunoglobulin | |
| Rituximab (Rituxan® & Truxima®) | Apr. 1, 2019 | • Changed policy title; previously titled Rituxan® (Rituximab)  
• Revised coverage rationale:  
  o Updated list of applicable drug products; added Truxima® (rituximab-abbs)  
  o 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 | |
## Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rituximab (Rituxan® &amp; Truxima®) <em>(continued)</em></td>
<td>Apr. 1, 2019</td>
<td>- 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: o Patient is positive for autoimmune encephalopathy antibody; and o Infectious causes (e.g., viral) of encephalitis have been ruled out o Added example of an autoimmune mucocutaneous</td>
<td>2. Corticosteroids 3. Immune globulin 4. Splenectomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>II. <strong>Autoimmune mucocutaneous blistering diseases (e.g. pemphigus vulgaris)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>III. <strong>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:</strong> A. Diagnosis of Wegener’s granulomatosis or microscopic polyangiitis; and B. <strong>One</strong> of the following: 1. Patient is receiving concurrent therapy with glucocorticoids 2. History of contraindication or intolerance to glucocorticoids</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>IV. <strong>Autoimmune hemolytic anemia, including chronic cold agglutinin disease</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>V. <strong>Rituximab is proven and medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met:</strong> A. Moderate to severe disease activity [e.g., swollen, tender joints with limited range of motion]; and B. <strong>One</strong> 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 <strong>one</strong> tumor necrosis factor (TNF) inhibitors [e.g., adalimumab (Humira), etanercept (Enbrel), infliximab (Remicade)]; and D. Patient is not receiving rituximab in combination with <strong>either</strong> of the following: 1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] 2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>VI. <strong>Post-transplant B-lymphoproliferative disorder</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>VII. <strong>Neuromyelitis optica</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>VIII. <strong>Rituximab is proven and medically necessary for the treatment</strong></td>
</tr>
</tbody>
</table>
## Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Rituximab    | Apr. 1, 2019   | Blistering disease: pemphigus vulgaris | 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  
- Polynuropathy 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. |
| (Rituxan® & Truxima®) (continued) |                | 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 |                   |
| Simponi Aria® | 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. |
| (Golimumab) Injection for Intravenous Infusion |                |                   |                   |
## Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
</table>
| **REVISED**                                      |                | **Simponi Aria® (Golimumab) Injection for Intravenous Infusion (continued)**  
  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**  
  o 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 inhibitor [e.g., Xeljanz (tofacitinib)]  
  **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) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]  
          b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]  
<p>| Apr. 1, 2019                                     |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                  |</p>
<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simponi Aria® (Golimumab) Injection for Intravenous Infusion (continued)</td>
<td>Apr. 1, 2019</td>
<td><strong>Psoriatic Arthritis</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Initial Therapy</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o 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)”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Continuation of Therapy</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o Added criteria requiring:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Documentation of positive clinical response to Simponi Aria; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ 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</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Patient is not receiving Simponi Aria in combination with any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]</td>
<td>[e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. For <strong>continuation therapy</strong>, all of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Documentation of positive clinical response to Simponi Aria; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Patient is <strong>not</strong> receiving Simponi Aria in combination with any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>c. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>III. Rheumatoid arthritis when all of the following criteria are met:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>A. For <strong>initial therapy</strong>, all of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Diagnosis of moderately to severely active rheumatoid arthritis (RA); and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. One of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Patient is receiving concurrent therapy with methotrexate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. History of contraindication or intolerance to methotrexite; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Patient is <strong>not</strong> receiving Simponi Aria in combination with either of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>B. For <strong>continuation therapy</strong>, all of the following:</td>
<td></td>
</tr>
</tbody>
</table>
### Medical Benefit Drug Policy Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong> Simponi Aria® (Golimumab) Injection for Intravenous Infusion (continued)</td>
<td>Apr. 1, 2019</td>
<td><strong>Cimzia (certolizumab), Orencia (abatacept)</strong>&lt;br&gt; 1. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]&lt;br&gt; 2. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]</td>
<td>1. Documentation of positive clinical response to Simponi Aria; <strong>and</strong>&lt;br&gt; 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); <strong>and</strong>&lt;br&gt; 3. Patient is <strong>not</strong> receiving Simponi Aria in combination with either of the following:&lt;br&gt; a. Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]&lt;br&gt; b. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]</td>
</tr>
</tbody>
</table>
### Medical Benefit Drug Policy Updates

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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
</table>
| **Stelara®** *(Ustekinumab)* *(continued)* | Apr. 1, 2019 | II. **Plaque psoriasis when all of the following criteria are met:**<br>A. Diagnosis of moderate to severe plaque psoriasis; **and**<br>B. Patient is a candidate for systemic therapy; **and**<br>C. Patient is unable to self-administer subcutaneous doses; **and**<br>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):<br>1. 45mg every 12 weeks for patients weighing ≤100kg subcutaneously<br>2. 90mg every 12 weeks for patients weighing >100kg subcutaneously<br>**and**<br>E. Patient is not receiving Stelara in combination with **any** of the following:<br>1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br><br>III. **Psoriatic arthritis when all of the following criteria are met:**<br>A. Diagnosis of psoriatic arthritis; **and**<br>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**<br>C. Patient is unable to self-administer subcutaneous doses; **and**<br>D. Patient is not receiving Stelara in combination with **any** of the following:<br>1. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]<br>2. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]<br>3. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]<br><br>**Stelara is unproven and not medically necessary for the treatment of multiple sclerosis.**<br>In available studies, Stelara does not demonstrate efficacy in the treatment of multiple sclerosis.
# Coverage Determination Guideline (CDG) Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UPDATED</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Breast</strong></td>
<td><strong>May 1, 2019</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Reconstruction Post Mastectomy** | | - Reorganized policy template:  
| | o Simplified and relocated *Instructions for Use*  
| | o Removed *Benefit Considerations* section  
| | - Updated coverage rationale:  
| | o Simplified content  
| | o 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”  
| | o 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:  
| | o Cosmetic Procedures (California only)  
| | o Mastectomy  
| | o 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:  
| | o Simplified content  
| | o 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  

---

*Note: The information provided is a summary of changes and is subject to the full document.*
### Coverage Determination Guideline (CDG) Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UPDATED</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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)  

---

**Medical Policy Update Bulletin: April 2019**
### Utilization Review Guideline (URG) Updates

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
<th>Coverage Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REVISED</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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**. | 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 |
| | | • 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 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. |