# oscar CG064 Concomitant Concurrent Biologics Instructions

Contents



## oscar CG064 Concomitant Concurrent Biologics

**Clinical Guideline**

Oscar Clinical Guideline: Concomitant (Concurrent) use of Biologics (Biologic Response Modifiers Therapies) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs) (CG064, Ver. 5) Concomitant (Concurrent) use of Biologics (Biologic Response Modifiers

Therapies) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs)

### Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of

Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

## Summary

Biologic response modifier therapies, or biologics, are specialized agents bioengineered to interact with specific aspects of the immune system. These unique therapeutics modulate the immune response and disrupt inflammation, playing a pivotal role in managing autoimmune diseases. Biologics, also recognized as immunomodulators and anticytokine agents, have a broad treatment scope encompassing conditions like axial ankylosing spondylitis, graft-versus-host disease, juvenile idiopathic arthritis, rheumatoid arthritis, psoriatic arthritis, psoriasis, and inflammatory bowel disease. Beyond autoimmune disorders, biologics also find usage in oncology, where they can target specific cancer cells or mitigate side effects of other cancer therapies. The administration routes for these drugs include intravenous, subcutaneous, and in some instances, oral delivery.

Classifications of biologics include soluble receptor antagonists, monoclonal antibodies, and cell surface receptor antagonist proteins, defined by their origin and function. Further subclassifications exist based on the mechanism of action and targeted therapy area, such as anti-integrin antibodies, B-cell inhibitors, Interleukin (IL) inhibitors, T-cell inhibitors, and Tumor Necrosis Factor (TNF) inhibitors.

**Table 1: Disease-modifying antirheumatic drugs (DMARDs)**

| Type of DMARD | Generic name | Example brand name(s) | Administration method |
|---|---|---|---|
| Conventional synthetic DMARDs | Azathioprine | Imuran, Azasan | Oral |
| | Hydroxychloroquine | Plaquenil | Oral |
| | Leflunomide | Arava | Oral |
| | Methotrexate | Rheumatrex, Trexall, Otrexup, Rasuvo | Oral or subcutaneous injection |
| | Sulfasalazine | Azulfidine, Azulfidine EN tabs | Oral |
| Biologic DMARDs | Abatacept | Orencia | Subcutaneous injection or intravenous infusion |
| | Adalimumab | Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry | Subcutaneous injection |
| | Anakinra | Kineret | Subcutaneous injection |
| | Belimumab | Benlysta | Subcutaneous injection or intravenous infusion |
| | Brodalumab | Siliq | Subcutaneous injection |
| | Canakinumab | Ilaris | Subcutaneous injection |
| | Certolizumab pegol | Cimzia | Subcutaneous injection |
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|---|---|---|---|
| | Etanercept | Enbrel | Subcutaneous injection |
| | Golimumab | Simponi | Subcutaneous injection or intravenous infusion |
| | Guselkumab | Tremfya | Subcutaneous injection |
| | Infliximab | Avsola, Inflectra, Ixifi, Remicade, Renflexis, Zymfentra | Subcutaneous injection or intravenous infusion |
| | Ixekizumab | Taltz | Subcutaneous injection |
| | Mirikizumab | Omvoh | Subcutaneous injection or intravenous infusion |
| | Natalizumab | Tysabri | Intravenous infusion |
| | Obinutuzumab | Gazyva | Intravenous infusion |
| | Ofatumumab | Arzerra, Kesimpta | Subcutaneous injection or intravenous infusion |
| | Risankizumab | Skyrizi | Subcutaneous injection or intravenous infusion |
| | Rituximab | Riabni, Rituxan, Ruxience, Truxima | Intravenous infusion |
| | Sarilumab | Kevzara | Subcutaneous injection |
| | Secukinumab | Cosentyx | Subcutaneous injection or intravenous infusion |
| | Tocilizumab | Actemra, Tofidence | Subcutaneous injection or intravenous infusion |
| | Ustekinumab | Stelara, Wezlana | Subcutaneous injection or intravenous infusion |
| Targeted synthetic DMARDs – Janus Associated Kinase (JAK) Inhibitors | Abrocitinib | Cibinqo | Oral |
| | Baricitinib | Olumiant | Oral |
| | Deucravacitinib | Sotyktu | Oral |
| | Fedratinib | Inrebic | Oral |
| | Momelotinib | Ojjaara | Oral |
| | Pacritinib | Vonjo | Oral |
| | Ritlecitinib | Litfulo | Oral |
| | Ruxolitinib | Jakafi | Oral |
| | Tofacitinib | Xeljanz/Xeljanz XR | Oral |
| | Upadacitinib | Rinvoq | Oral |

| | | | |
|---|---|---|---|
| Targeted synthetic DMARDs – Phosphodiesterase-4 (PDE-4 ) Inhibitors | Apremilast | Otezla | Oral |

NOTE: The above table provides a selection of the commonly prescribed DMARDs in the United States.

It is important to note that this table is not exhaustive, and it may not include some recently approved drugs or those currently under investigation.

- Oral tsDMARDs coverage is subject to Plan benefits and are typically billed through a member's pharmacy benefits.

## Definitions

**Biologic drug class by type of therapeutic molecule/agent:**

- Cell surface receptor antagonist proteins" are inactive proteins that compete with cytokines for binding sites on the cytokine's membrane receptor. The percentage of receptors they need to bind to for effective action can vary depending on the specific drug and condition being treated.
- Monoclonal antibodies"are laboratory-produced antibodies derived from human or nonhuman sources, engineered to target and recognize specific antigens causing disease. Their affinity for antigens is greater than that of soluble receptor antagonists.
- Soluble receptor antagonists"are molecules that selectively bind to target cytokines present in the blood, thus preventing the cytokines from interacting with cell surface receptors.

**Biologic response modifier therapies (biologics) drug class by mechanism of action and area of target:**

- "Anti-integrin antibody" specifically bind to and inhibit the interaction between integrin alpha-4-beta-7 and mucosal addressin cell adhesion molecule-1 (MAdCAM-1) in the gut, thus reducing chronic inflammation associated with ulcerative colitis and Crohn's disease. Natalizumab and vedolizumab are FDA-approved anti-integrin drugs.
- "B-cells inhibitors" impede the activation of B-cells, the cells initiating a cascade reaction resulting in inflammation. B-cell inhibitors include rituximab and belimumab.
- "Interleukin (IL) inhibitors" target interleukins, which are key mediators of inflammation in the body. Anakinra, canakinumab, and rilonacept are common IL-1 inhibitors. IL-6 inhibitors include tocilizumab and sarilumab, while IL-17 inhibitors comprise secukinumab, ixekizumab, or brodalumab. Ustekinumab is a common IL-12/23 inhibitor. Newer IL-23 inhibitors like guselkumab and risankizumab specifically target the p19 subunit of IL-23, providing more selective inhibition.
- "T-cells inhibitors" impede the activation of cytokines influencing systemic inflammation. An example of a T-cell co-stimulation blocker is abatacept.
- "Tumor Necrosis Factor (TNF) inhibitors" specifically target tumor necrosis factor-alpha, an inflammatory cytokine implicated in cell death during inflammation. They halt this inflammatory process and slow disease progression. Examples include infliximab, adalimumab, certolizumab, etanercept, golimumab.

“Concomitant” refers to the use of two or more drugs together as part of a treatment regimen.

“Disease-modifying antirheumatic drugs (DMARDs)” are a class of drugs that modulate the immune system and inflammation. They are categorized as:

1. Conventional/traditional DMARDs: e.g., methotrexate, sulfasalazine, hydroxychloroquine, leflunomide. They are typically the first line of therapy.
2. Biologic DMARDs: These include many of the biologics mentioned above, typically used in patients who do not respond to initial therapy for rheumatoid arthritis. However, it’s important to note that not all biologics are necessarily categorized as DMARDs, as some are used for conditions other than rheumatic diseases.
3. Targeted synthetic DMARDs (tsDMARDs): e.g., baricitinib, tofacitinib, apremilast. They are generally prescribed for patients who have failed or have contraindications to conventional DMARDs or biologic DMARDs.

“Kinase inhibitors” are small-molecule drugs not made from recombinant DNA or proteins; thus, they are not considered biologics. They inhibit various kinases, including Janus kinases (JAK), which are critical for cellular signal transduction pathways. These orally administered medications include tofacitinib and baricitinib, which specifically target JAK, but other kinase inhibitors may target different kinases.

**Policy Statement on Concomitant (Concurrent) use of Biologics (Biologic Response Modifiers**

Therapies) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs)

The concurrent use of two or more biologic agents or a biologic agent with a targeted synthetic DMARD (tsDMARD) for the same diagnosis during the same time period is typically considered experimental or investigational and is not considered medically necessary, unless supported by FDA guidelines, clinical criteria, or high-quality clinical evidence.

- Concomitant use of multiple biologics may increase the risk of infection without providing additional clinical benefit.
- Clinical trials have not demonstrated added benefit from concomitant use of certain biologics.
- Current treatment guidelines from major rheumatology and dermatology societies do not recommend routine concurrent use of biologics or biologics with tsDMARDs.

Medical Necessity Criteria for Concomitant (Concurrent) use of Biologics (Biologic Response

Modifiers Therapies) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs)

The Plan does not consider medically necessary the concurrent use of a biologic when the following criteria are met:

1. The use of two or more biologic agents (Anti-integrin antibody, B-cell inhibitors, IL inhibitors, Tcell inhibitors, TNF inhibitors), for purposes of the same diagnosis during the same time period (unless indicated that there is greater efficacy with concurrent use of biologics by FDA prescribing guidelines, compendia, national society guidelines, clinical criteria or high-quality clinical evidence); or

2. The use of a biologic agent with a targeted synthetic DMARD (tsDMARD), for purposes of the same diagnosis during the same time period, (unless indicated that there is greater efficacy with concurrent use of biologics by FDA prescribing guidelines, compendia, national society guidelines, clinical criteria or high-quality clinical evidence) including but not limited to:

a. An oral Janus kinase (JAK) inhibitor (e.g., Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), Xeljanz XR (tofacitinib)); or

b. An oral phosphodiesterase-4 (PDE4) inhibitor (e.g., Otezla (apremilast)).

**Rationale:**

The current body of evidence is not sufficient to confirm the medical benefits of concurrent use of Biologic Response Modifiers Therapies (biologics) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs). Based on the Plan's review of the available clinical evidence, the Plan maintains the following position:

1. There is not enough information to establish definitive medical necessity criteria for coverage.

2. In line with current evidence, the Plan advises against the concurrent use of biologics and tsDMARDs for the same diagnosis during the same time period, as there is insufficient evidence supporting such practice. This stance prioritizes the safety of our members and directs their treatment towards evidence-based, effective regimens.

3. The concurrent use of these therapies will be classified as experimental, investigational, and unproven until robust clinical evidence suggesting otherwise becomes available.

The Plan considers the concomitant use of various classes of biologic agents including Antiintegrin antibody, B-cell inhibitors, IL inhibitors, and T-cell inhibitors, as well as concomitant use of biologic agents with tsDMARDs, such as JAK inhibitors and PDE4 inhibitors, not medically necessary unless specifically indicated in FDA prescribing guidelines, compendia, national society guidelines, clinical criteria or high-quality clinical evidence

4. National societies such as the American College of Gastroenterology, American College of Rheumatology, American Academy of Dermatology, National Comprehensive Cancer Network, and National Psoriasis Foundation, currently do not include concurrent use of biologics in their general guidance.

5. FDA prescribing labels often discourage simultaneous usage due to increased risk of severe infections and potential drug interactions.

6. Clinical studies of drugs like Abatacept (Orencia), a T-cell co-stimulation blocker, have failed to demonstrate any enhanced efficacy with concurrent treatment. Instead, patients experienced increased rates of infections and serious infections. The use of TNF inhibitors in conjunction with other biologic agents also lacks compelling evidence supporting its safety and efficacy.

**Experimental or Investigational / Not Medically Necessary**

The Plan considers concomitant use of Biologic Response Modifiers Therapies (biologics) and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs) to be not medically necessary primarily due to lack of substantial high-quality clinical evidence, showing a clear and significant benefit to members when these treatments are used concurrently.

Most of the current scientific evidence and clinical guidelines advocate for a stepwise approach in the treatment of autoimmune diseases, beginning with conventional synthetic DMARDs, then moving to biologics or tsDMARDs if necessary. The simultaneous use of two or more biologics or a combination of a biologic with a tsDMARD is generally not supported by these guidelines, primarily due to concerns about increased risk of severe side effects, such as serious infections, without a commensurate increase in therapeutic benefit.

The concurrent use of these treatments can also compound their individual side effects, potentially posing increased risk of harm to the member. As such, until there is clear, robust evidence from well-designed clinical trials showing that the combined use of these treatments offers substantial benefits that outweigh the potential risks, such use will be considered experimental, investigational, and unproven.

## Concomitant Use of Biologics

The concomitant use of multiple biologics generally increases the susceptibility to infection and is not routinely recommended. Practice guidelines from national societies such as the American College of Gastroenterology, American College of Rheumatology, American Academy of Dermatology, National Comprehensive Cancer Network, National Psoriasis Foundation do not generally endorse the concurrent use of biologics (B-cell inhibitors, IL inhibitors, T-cell inhibitors, TNF inhibitors) as part of standard treatment protocols. The Plan recognizes that in certain refractory cases, some recent studies have explored combination therapies under close monitoring. Please consult the most recent FDA prescribing labels for specific indications, contraindications, warnings, and precautions.

## Concomitant use of Anti-integrin antibody

The Plan does not consider medically necessary the use of anti-integrin antibodies (e.g., Tysabri (natalizumab), Entyvio (vedolizumab)) concurrently with another anti-integrin antibody or TNF inhibitors due to the risk of drug interactions and increased infections, as per current prescribing labels.

### Concomitant use of B-cells inhibitors

### Other biologics

The Plan does not consider medically necessary the concomitant use of B-cell inhibitors with other biologics due to limited evidence. This includes newer B-cell targeting therapies such as obinutuzumab and ofatumumab.

## Concomitant Use of IL inhibitors

### Other biologics

The Plan does not consider medically necessary the concurrent use of IL inhibitors (e.g., Kineret (anakinra), Tremfya (guselkumab), Skyrizi (risankizumab)) with TNF blockers (e.g., infliximab), as there is no established added clinical benefit per FDA labels. Concurrent use of IL inhibitors (e.g., ustekinumab) with other biologic agents has not been sufficiently evaluated in clinical studies for most conditions. However, emerging research in inflammatory bowel disease suggests potential benefits in certain refractory cases, which may be considered on a case-bycase basis.

### Concomitant use a of Janus kinase (JAK) inhibitor

The Plan does not consider medically necessary the concurrent use of JAK inhibitors (including but not limited to Rinvoq (upadacitinib), Olumiant (baricitinib), Xeljanz (tofacitinib), Cibinqo (abrocitinib), Sotyktu (deucravacitinib), Inrebic (fedratinib), Jakafi (ruxolitinib)) with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine and cyclosporine. These combinations are not recommended in current prescribing labels due to increased risk of immunosuppression without established additional benefit.

### Concomitant Use of T-cell co-stimulation blocker

TNF Inhibitor, Biologic DMARDs, JAK inhibitors

The Plan does not consider medically necessary the use of T-cell co-stimulation blockers when prescribed with a TNF inhibitor, other biologic DMARDs, or JAK inhibitors, as it is not recommended per FDA labels. The ORENCIA STUDY IV clinical trial demonstrated no benefit and increased risk of infections with concurrent use of abatacept (Orencia) and TNF inhibitor therapy.

**Concomitant use of Phosphodiesterase-4 (PDE4) inhibitors**

PDE4 inhibitors (e.g., Otezla (apremilast)) are not recommended for use concurrently with biologics for Behçet's Disease, moderate-to-severe plaque psoriasis, or active psoriatic arthritis.
They should be used as an alternative for members who have failed or have contraindications to conventional DMARDs and/or biologics, as per current clinical pharmacology data and drug interaction databases.

## Concomitant Use of TNF inhibitors

**Other biologics**

The Plan does not consider medically necessary the use of TNF inhibitors (e.g., infliximab, etanercept, adalimumab) concurrently with other biologic agents such as IL inhibitors or biologic agents in different drug classes, due to insufficient evidence on safety and efficacy as per FDA guidelines. While some recent small-scale studies in inflammatory bowel disease have explored combination therapy with TNF inhibitors and IL inhibitors, these approaches remain experimental and raise safety concerns. Any such combinations should only be considered in highly refractory cases under expert care and close monitoring, which may be considered on a case-by-case basis.

**Biosimilars**

The above guidance applies equally to reference biologics and their approved biosimilars. The use of biosimilars should follow the same principles of monotherapy or limited combination therapy as their reference products.

Applicable Billing Codes (HCPCS/CPT Codes)

## Disclaimer

The codes for products listed below are provided for informational purposes only. Inclusion or exclusion of a code does not imply or guarantee coverage or reimbursement by the Plan.
The actual coverage or non-coverage of services for an individual member will be determined by the terms and conditions of their policy at the time of service, as well as applicable state and federal law.

For confirmation of coverage, please refer to the member's policy documents, such as the Certificate/Evidence of Coverage, Schedule of Benefits, or Plan Formulary. Alternatively, the Plan can be directly contacted for confirmation. The provision of services is governed by the terms, conditions, and limitations of a member's policy.

As outlined in the aforementioned policy, concurrent use of biologics is not typically considered medically necessary. Coverage for a singular biologic is dependent on the members' plan benefits and adherence to the Plan's Clinical Guidelines, including but not limited to the Commercial Preferred Physician-Administered Specialty Drugs (CG052).

| **CPT/HCPCS Codes for biologics** | | |
|---|---|---|
| Anti-integrin antibodies | | |
| J2323 | Injection, natalizumab, 1 mg | |
| Q5134 | Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg | |
| J3380 | Injection, vedolizumab, intravenous, 1 mg | |
| C9399/J3590 | [vedolizumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |

| B-cell inhibitors | | |
|---|---|---|
| Code | Description | |
| J0490 | Injection, belimumab, 10 mg | |
| J3590 | [belimumab (SC)] Unclassified biologics | |
| J9301 | Injection, obinutuzumab, 10 mg | |
| J9302 | Injection, ofatumumab, 10 mg | |
| C9399/J3590 | [ofatumumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| J9311 | Injection, rituximab 10 mg and hyaluronidase | |
| J9312 | Injection, rituximab, 10 mg | |
| Q5115 | Injection, rituximab-abbs, biosimilar, (truxima), 10 mg | |
| Q5119 | Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg | |
| Q5123 | Injection, rituximab-arrx, biosimilar, (riabni), 10 mg | |
| Janus Associated Kinase (JAK) Inhibitors | | |
| J8499 | [Abrocitinib] Prescription drug, oral, non chemotherapeutic, nos | |
| J8499 | [Baricitinib] Prescription drug, oral, non chemotherapeutic, nos | |
| J8499 | [Deucravacitinib] Prescription drug, oral, non chemotherapeutic, nos | |
| C9399/J8499 | [Fedratinib] Unclassified drugs or biologicals/Prescription drug, oral, non chemotherapeutic, nos | |
| C9399/J8499 | [Momelotinib] Unclassified drugs or biologicals/Prescription drug, oral, non chemotherapeutic, nos | |
| C9399/J8499 | [Pacritinib] Unclassified drugs or biologicals/Prescription drug, oral, non chemotherapeutic, nos | |
| J8499 | [Ritlecitinib] Prescription drug, oral, non chemotherapeutic, nos | |
| C9399/J8499 | [Ruxolitinib] Unclassified drugs or biologicals/Prescription drug, oral, non chemotherapeutic, nos | |
| J8499 | [Tofacitinib, tofacitinib citrate ER] Prescription drug, oral, non chemotherapeutic, nos | |
| J7999 | [tofacitinib citrate (bulk powder)] Compounded drug, not otherwise classified | |
| J8499 | [Upadacitinib] Prescription drug, oral, non chemotherapeutic, nos | |
| Interleukin inhibitors | | |
| C9399/J3590 | [Anakinra (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [Brodalumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [Ixekizumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9168 | Injection, mirikizumab-mrkz, 1 mg | |
| J2267 | Injection, mirikizumab-mrkz, 1 mg<br>Code Note: Code becomes effective 7/1/24 | |

| | | |
|---|---|---|
| C9399/J3590 | [mirikizumab-mrkz (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| J2327 | Injection, risankizumab-rzaa, intravenous, 1 mg | |
| C9399/J3590 | [Risankizumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [Sarilumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9166 | Injection, secukinumab, intravenous, 1 mg | |
| J3247 | Injection, secukinumab, intravenous, 1 mg<br>Code Note: Code becomes effective 7/1/24 | |
| C9399/J3590 | [Secukinumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| J0638 | Injection, canakinumab, 1 mg | |
| J1628 | Injection, guselkumab, 1 mg | |
| J2793 | Injection, rilonacept, 1 mg | |
| J3262 | Injection, tocilizumab, 1 mg | |
| Q5133 | Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg | |
| C9399/J3590 | [tocilizumab (SC)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [tocilizumab-aazg (Tyenne)] Unclassified drugs or biologicals/Unclassified biologics | |
| J3357 | Ustekinumab, for subcutaneous injection, 1 mg | |
| J3358 | Ustekinumab, for intravenous injection, 1 mg | |
| Q5137 | Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg<br>Code Note: Code becomes effective 7/1/24 | |
| Q5138 | Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg | |
| | Code Note: Code becomes effective 7/1/24 | |
| Phosphodiesterase-4 (PDE-4) Inhibitors | | |
| J8499 | [Apremilast] Prescription drug, oral, non chemotherapeutic, nos | |
| T-cell inhibitors | | |
| J0129 | Injection, abatacept, 10 mg (code may be used for Medicare when drug administered und er the direct supervision of a physician, not for use when drug is self-administered) | |
| J0485 | Injection, belatacept, 1 mg | |
| TNF inhibitors | | |
| J0135 | Injection, adalimumab, 20 mg | |
| C9399/J3590 | [adalimumab-ryvk (Simlandi)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [adalimumab-bwwd (Hadlima)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [adalimumab-fkjp (Hulio)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [adalimumab-atto (Amjevita)] Unclassified drugs or biologicals/Unclassified biologics | |
| C9399/J3590 | [adalimumab-adaz (Hyrimoz)] Unclassified drugs or biologicals/Unclassified biologics | |

| | |
|---|---|
| C9399/J3590 | [adalimumab-aqvh (Yusimry)] Unclassified drugs or biologicals/Unclassified biologics |
| C9399/J3590 | [adalimumab-adbm (Cyltezo)] Unclassified drugs or biologicals/Unclassified biologics |
| C9399/J3590 | [adalimumab-aaty (Yuflyma)] Unclassified drugs or biologicals/Unclassified biologics |
| Q5131 | Injection, adalimumab-aacf (idacio), biosimilar, 20 mg |
| Q5132 | Injection, adalimumab-afzb (abrilada), biosimilar, 10 mg |
| J0717 | Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered) |
| J1438 | Injection, etanercept, 25 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered) |
| J1602 | Injection, golimumab, 1 mg, for intravenous use |
| C9399/J3590 | [golimumab (SC)] Unclassified drugs or biologicals/Unclassified biologics |
| J1745 | Injection, infliximab, excludes biosimilar, 10 mg |
| J1748 | Injection, infliximab-dyyb (zymfentra), 10 mg |
| C9399/J3590 | [infliximab-dyyb (SC)] Unclassified drugs or biologicals/Unclassified biologics |
| Q5103 | Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg |
| Q5104 | Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg |
| Q5109 | Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg |
| Q5121 | Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg |
| ICD-10 codes considered NOT medically necessary: | |
| Code | Description |
| Z79 | Long term (current) drug therapy |
| Z79.6 | Long term (current) use of immunomodulators and immunosuppressants |
| Z79.62 | Long term (current) use of immunosuppressant |
| Z79.61 | Long term (current) use of immunomodulator |
| Z79.620 | Long term (current) use of immunosuppressive biologic |
| Z79.622 | Long term (current) use of J anus kinase inhibitor |

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**Specifications:**

- Product Name: Clinical Guideline – Concomitant Use of Biologics and tsDMARDs
- Version: 5
- Classifications: Biologics and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs)

## Product Information:

The Clinical Guideline provides evidence-based criteria for the concurrent use of Biologics and targeted synthetic Disease-Modifying Antirheumatic Drugs (tsDMARDs). It includes classifications of biologics based on origin, function, and mechanism of action. The guideline also lists various types of DMARDs and their administration methods.

## Product Usage Instructions:

#### Classifications of Biologics:

Biologics are classified into soluble receptor antagonists, monoclonal antibodies, and cell surface receptor antagonist proteins. Subclassifications include anti-integrin antibodies, B-cell inhibitors, IL inhibitors, T-cell inhibitors, and TNF inhibitors.

## Disease-Modifying Antirheumatic Drugs (DMARDs):

The guideline lists conventional synthetic DMARDs and biologic DMARDs along with their generic names, example brand names, and administration methods (oral, subcutaneous injection, or intravenous infusion).

## Targeted Synthetic DMARDs – JAK Inhibitors:

This category includes JAK inhibitors with different brand names and administration methods such as subcutaneous injection or intravenous infusion.

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## FAQ:

#### Q: Can I use multiple biologics simultaneously?

A: The guideline specifically addresses the concurrent use of biologics and tsDMARDs. It is recommended to follow the provided clinical criteria and consult healthcare professionals for personalized recommendations.

#### Q: What should I do if I miss a dose of my DMARD?

A: If you miss a dose of your DMARD, follow the specific instructions provided by your healthcare provider or refer to the product label. Do not double the dose to make up for a missed one.

## Documents / Resources

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|  | oscar CG064 Concomitant Concurrent Biologics [pdf] Instructions<br>CG064, Ver. 5, CG064 Concomitant Concurrent Biologics, CG064, Concomitant Concurrent Biologics, Concurrent Biologics, Biologics |

## References


- Arthritis Foundation | Arthritis Support, Resources, Research & Advocacy
- Comprehensive Cancer Information - NCI
- Evidence-based Clinical Solutions for Healthcare | UpToDate | Wolters Kluwer
- ClinicalKey
- Redirecting
- These highlights do not include all the information needed to use OLUMIANT safely and effectively. See full prescribing information for OLUMIANT.OLUMIANT (baricitinib) tablets, for oral useInitial U.S. Approval: 2018
- Login - Clinical Pharmacology
- Resources for You (Biologics) | FDA
- Biologic Response Modifiers (BRMs) - StatPearls - NCBI Bookshelf
- User Manual