CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 3248-D |

**This document applies to the following:**

| Formulary | Applies |
| --- | --- |
| Standard Control (SF) |  |
| Standard Control – Choice (SCCF) |  |
| Preferred Drug Plan Design (PDPD) |  |
| Advanced Control Specialty (ACSF) |  |
| Advanced Control Specialty – Choice (ACSCF) |  |
| Managed Medicaid Template (MMT) |  |
| Marketplace (MF) |  |
| Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE) |  |
| Aetna Individual Lives (IVL) |  |
| Value (VF) |  |
| New to Market (NTM) |  |

| Formulary | Applies |
| --- | --- |
| Standard Formulary Chart (SFC) |  |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) |  |
| Advanced Control Specialty Formulary Chart (ACSFC) |  |
| Value Formulary Chart (VFC) |  |
| Medical Benefit |  |
| Medical Benefit: Advanced Biosimilars First |  |
| Combined Benefit Medical (CBM) |  |
| Combined Benefit Medical Pharmacy (CBMP) |  |
| Medical Benefit: Managed Medicaid (MMMB) |  |
| Medicare Part B |  |
| Medicare Part B: Advanced Biosimilars First |  |

# Exceptions Criteria Autoimmune Conditions

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Managed Medicaid Template (MMT).

## Plan Design Summary

This program applies to the autoimmune drug products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to any of the following:

* For plaque psoriasis, all members requesting treatment with a targeted product.
* For all other indications, all members requesting treatment with Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita, Cyltezo, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, Yuflyma, Yusimry, and Zymfentra, and all members who are new to treatment with all other targeted products for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

### Table. Drugs For Autoimmune Conditions

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

Abbreviations: IV = intravenous, SC = subcutaneous

#### Indication: Ankylosing Spondylitis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Avsola (infliximab-axxq) * Cosentyx (SC) (secukinumab) * Enbrel (etanercept) * Hadlima (adalimumab-bwwd) * Rinvoq (upadacitinib) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Bimzelx (bimekizumab-bkzx) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Inflectra (infliximab-dyyb) * Remicade (infliximab) * Renflexis (infliximab-abda) * Simlandi (adalimumab-ryvk) * Simponi (golimumab) * Simponi Aria (golimumab) * Taltz (ixekizumab) * Xeljanz/Xeljanz XR (tofacitinib) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Crohn’s Disease

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Avsola (infliximab-axxq) * Entyvio (IV/SC) (vedolizumab) * Hadlima (adalimumab-bwwd) * Rinvoq (upadacitinib) * Skyrizi (IV/SC) (risankizumab-rzaa) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Inflectra (infliximab-dyyb) * Omvoh (IV/SC) (mirikizumab-mrkz) * Remicade (infliximab) * Renflexis (infliximab-abda) * Simlandi (adalimumab-ryvk) * Stelara (IV/SC) (ustekinumab) * Tremfya (IV/SC) (guselkumab) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) * Zymfentra (infliximab-dyyb) |

#### Indication: Hidradenitis Suppurativa

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Cosentyx (SC) (secukinumab) * Hadlima (adalimumab-bwwd) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Bimzelx (bimekizumab-bkzx) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Simlandi (adalimumab-ryvk) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Non-Radiographic Axial Spondyloarthritis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * Cosentyx (SC) (secukinumab) * Rinvoq (upadacitinib) | * Bimzelx (bimekizumab-bkzx) * Cimzia (certolizumab pegol) * Taltz (ixekizumab) |

#### Indication: Plaque Psoriasis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Avsola (infliximab-axxq) * Cosentyx (SC) (secukinumab) * Enbrel (etanercept) * Hadlima (adalimumab-bwwd) * Otezla (apremilast) * Skyrizi (SC) (risankizumab-rzaa) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Bimzelx (bimekizumab-bkzx) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Ilumya (tildrakizumab-asmn) * Inflectra (infliximab-dyyb) * Remicade (infliximab) * Renflexis (infliximab-abda) * Siliq (brodalumab) * Simlandi (adalimumab-ryvk) * Sotyktu (deucravacitinib) * Stelara (SC) (ustekinumab) * Taltz (ixekizumab) * Tremfya (SC) (guselkumab) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Polyarticular Juvenile Idiopathic Arthritis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Enbrel (etanercept) * Hadlima (adalimumab-bwwd) * Rinvoq (upadacitinib) | * Abrilada (adalimumab-afzb) * Actemra (IV/SC)/Actemra Actpen (tocilizumab) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Orencia (IV/SC)/Orencia ClickJect (abatacept) * Simlandi (adalimumab-ryvk) * Simponi Aria (golimumab) * Tofidence (IV) (tocilizumab-bavi) * Tyenne (IV/SC) (tocilizumab-aazg) * Xeljanz/Xeljanz XR (tofacitinib) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Psoriatic Arthritis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Avsola (infliximab-axxq) * Cosentyx (SC) (secukinumab) * Enbrel (etanercept) * Hadlima (adalimumab-bwwd) * Otezla (apremilast) * Rinvoq (upadacitinib) * Skyrizi (SC) (risankizumab-rzaa) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Bimzelx (bimekizumab-bkzx) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Inflectra (infliximab-dyyb) * Orencia (IV/SC)/Orencia ClickJect (abatacept) * Remicade (infliximab) * Renflexis (infliximab-abda) * Simlandi (adalimumab-ryvk) * Simponi (golimumab) * Simponi Aria (golimumab) * Stelara (SC) (ustekinumab) * Taltz (ixekizumab) * Tremfya (SC) (guselkumab) * Xeljanz/Xeljanz XR (tofacitinib) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Rheumatoid Arthritis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| adalimumab-adazadalimumab-fkjpAvsola (infliximab-axxq)Enbrel (etanercept)Hadlima (adalimumab-bwwd)Kevzara (sarilumab)Rinvoq (upadacitinib) | * Abrilada (adalimumab-afzb) * Actemra (IV/SC)/Actemra Actpen (tocilizumab) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Cimzia (certolizumab pegol) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Inflectra (infliximab-dyyb) * Kineret (anakinra) * Olumiant (baricitinib) * Orencia (IV/SC)/Orencia ClickJect (abatacept) * Remicade (infliximab) * Renflexis (infliximab-abda) * Simlandi (adalimumab-ryvk) * Simponi (golimumab) * Simponi Aria (golimumab) * Tofidence (IV) (tocilizumab-bavi) * Tyenne (IV/SC) (tocilizumab-aazg) * Xeljanz/Xeljanz XR (tofacitinib) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

#### Indication: Ulcerative Colitis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Avsola (infliximab-axxq) * Entyvio (IV/SC) (vedolizumab) * Hadlima (adalimumab-bwwd) * Rinvoq (upadacitinib) * Skyrizi (IV/SC) (risankizumab-rzaa) * Velsipity (etrasimod) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Inflectra (infliximab-dyyb) * Omvoh (IV/SC) (mirikizumab-mrkz) * Remicade (infliximab) * Renflexis (infliximab-abda) * Simlandi (adalimumab-ryvk) * Simponi (golimumab) * Stelara (IV/SC) (ustekinumab) * Tremfya (IV/SC) (guselkumab) * Xeljanz/Xeljanz XR (tofacitinib) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) * Zeposia (ozanimod) * Zymfentra (infliximab-dyyb) |

#### Indication: Uveitis

| Preferred Product(s) | Targeted Product(s) |
| --- | --- |
| * adalimumab-adaz * adalimumab-fkjp * Hadlima (adalimumab-bwwd) | * Abrilada (adalimumab-afzb) * adalimumab-aacf * adalimumab-aaty * adalimumab-adbm * adalimumab-ryvk * Amjevita (adalimumab-atto) * Cyltezo (adalimumab-adbm) * Hulio (adalimumab-fkjp) * Humira (adalimumab) * Hyrimoz (adalimumab-adaz) * Idacio (adalimumab-aacf) * Simlandi (adalimumab-ryvk) * Yuflyma (adalimumab-aaty) * Yusimry (adalimumab-aqvh) |

## Exception Criteria

### Plaque Psoriasis

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Avsola, Cosentyx SC, Enbrel, Otezla, and Skyrizi SC), unless there is a documented clinical reason to avoid tumor necrosis factor (TNF) inhibitors (see Appendix A).
* The requested product is a targeted infliximab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to the preferred infliximab product (Avsola), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Cosentyx SC, Enbrel, Otezla, and Skyrizi SC).
* The requested product is a targeted adalimumab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to all of the preferred adalimumab products (adalimumab-adaz, adalimumab-fkjp, and Hadlima), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Avsola, Cosentyx SC, Enbrel, Otezla, and Skyrizi SC).
* The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.

### Psoriatic Arthritis

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with at least six of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Avsola, Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or Janus kinase (JAK) inhibitors (see Appendix B), then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is a targeted infliximab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to the preferred infliximab product (Avsola), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with at least five of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
* The requested product is a targeted adalimumab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to all of the preferred adalimumab products (adalimumab-adaz, adalimumab-fkjp, and Hadlima), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with at least five of the preferred products (Avsola, Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
* The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
* The requested product is Bimzelx, Cimzia, Orencia IV/SC/Orencia ClickJect, Simponi, Simponi Aria, Stelara SC, Taltz, Tremfya SC, or Xeljanz/Xeljanz XR, and the member is currently receiving treatment with the requested product, excluding when it is obtained as samples or via manufacturer’s patient assistance programs.

### Crohn’s Disease

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Avsola, Entyvio IV/SC, Rinvoq, and Skyrizi IV/SC). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see Appendix B), or is a documented primary non-responder to an interleukin-23 (IL-23) inhibitor, then the member would not need to use the corresponding preferred product(s) from the respective class.
* The requested product is a targeted infliximab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to the preferred infliximab product (Avsola), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Entyvio IV/SC, Rinvoq, and Skyrizi IV/SC). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B) or is a documented primary non-responder to an IL-23 inhibitor, then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is a targeted adalimumab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to all of the preferred adalimumab products (adalimumab-adaz, adalimumab-fkjp, and Hadlima), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Avsola, Entyvio IV/SC, Rinvoq, and Skyrizi IV/SC). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B) or is a documented primary non-responder to an IL-23 inhibitor, then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
* The requested product is Omvoh SC and the member received Omvoh IV for induction therapy.
* The requested product is Stelara SC and the member received Stelara IV for induction therapy.
* The requested product is Tremfya SC and the member received Tremfya IV for induction therapy.
* The requested product is Cimzia, Omvoh IV/SC, Stelara IV/SC, or Tremfya IV/SC, and the member is currently receiving treatment with the requested product, excluding when it is obtained as samples or via manufacturer’s patient assistance programs.

### Ulcerative Colitis

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Avsola, Entyvio IV/SC, Rinvoq, Skyrizi IV/SC, and Velsipity). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see Appendix B), or is a documented primary non-responder to an IL-23 inhibitor, then the member would not need to use the corresponding preferred product(s) from the respective class.
* The requested product is a targeted infliximab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to the preferred infliximab product (Avsola), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Entyvio IV/SC, Rinvoq, Skyrizi IV/SC, and Velsipity). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B) or is a documented primary non-responder to an IL-23 inhibitor, then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is a targeted adalimumab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to all of the preferred adalimumab products (adalimumab-adaz, adalimumab-fkjp, and Hadlima), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Avsola, Entyvio IV/SC, Rinvoq, Skyrizi IV/SC, and Velsipity). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B) or is a documented primary non-responder to an IL-23 inhibitor, then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is Omvoh SC and the member received Omvoh IV for induction therapy.
* The requested product is Stelara SC and the member received Stelara IV for induction therapy.
* The requested product is Tremfya SC and the member received Tremfya IV for induction therapy.
* The requested product is Omvoh IV/SC, Simponi, Stelara IV/SC, Tremfya IV/SC, Xeljanz/Xeljanz XR, or Zeposia, and the member is currently receiving treatment with the requested product, excluding when it is obtained as samples or via manufacturer’s patient assistance programs.

### Non-Radiographic Axial Spondyloarthritis

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with either of the preferred products (Cosentyx SC or Rinvoq).
* The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
* Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer’s patient assistance programs.

### All Other Indications

Coverage for a targeted product is provided when any of the following criteria is met:

* Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Avsola, Cosentyx SC, Enbrel, Kevzara, and Rinvoq) where the products’ indications overlap. If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see Appendix B), then the member would not need to use the corresponding preferred products from the respective class.
* The requested product is a targeted infliximab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to the preferred infliximab product (Avsola), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hadlima], Cosentyx SC, Enbrel, Kevzara, and Rinvoq) where the products’ indications overlap, unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
* The requested product is a targeted adalimumab product, and the member meets both of the following:
  + Member has had a documented intolerable adverse event to all of the preferred adalimumab products (adalimumab-adaz, adalimumab-fkjp, and Hadlima), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
  + Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Avsola, Cosentyx SC, Enbrel, Kevzara, and Rinvoq) where the products’ indications overlap, unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
* The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
* The requested product is Actemra IV/SC/Actemra Actpen, Bimzelx, Cimzia, Kineret, Olumiant, Orencia IV/SC/Orencia ClickJect, Simponi, Simponi Aria, Taltz, Tofidence IV, Tyenne IV/SC, or Xeljanz/Xeljanz XR, and the member is currently receiving treatment with the requested product, excluding when it is obtained as samples or via manufacturer’s patient assistance programs.

## Appendix

### Appendix A: Clinical Reasons to Avoid TNF Inhibitors

* History of demyelinating disorder
* History of congestive heart failure
* History of hepatitis B virus infection
* Autoantibody formation/lupus-like syndrome
* History or risk of lymphoma or other malignancy
* History of being a primary non-responder to a TNF inhibitor

### Appendix B: Clinical Reasons to Avoid JAK Inhibitors

* History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy
* History or risk of major adverse cardiovascular events (MI, stroke, etc.)
* History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.)
* History of hepatitis B or hepatitis C virus infection
* History of being a primary non-responder to a JAK inhibitor

## References

1. Abrilada [package insert]. New York, NY: Pfizer Inc.; April 2024.
2. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
3. adalimumab-aacf [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; June 2024.
4. adalimumab-aaty [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2025.
5. adalimumab-adaz [package insert]. Princeton, NJ: Sandoz Inc.; November 2024.
6. adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
7. adalimumab-fkjp [package insert]. Cambridge, MA: Biocon Biologics Inc.; December 2023.
8. adalimumab-ryvk [package insert]. Leesburg, VA: Alvotech USA Inc.; February 2025.
9. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2024.
10. Avsola [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
11. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024.
12. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
13. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.
14. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
15. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; October 2024.
16. Entyvio [package insert]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; May 2024.
17. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; June 2024.
18. Hulio [package insert]. Cambridge, MA: Biocon Biologics Inc.; February 2025.
19. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
20. Hyrimoz [package insert]. Princeton, NJ: Sandoz Inc.; April 2024.
21. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; January 2024.
22. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
23. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
24. Kevzara [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC/Regeneron Pharmaceuticals, Inc.; August 2024.
25. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); September 2024.
26. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
27. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; January 2025.
28. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.
29. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
30. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
31. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; December 2023.
32. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2025.
33. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; August 2024.
34. Simlandi [package insert]. Leesburg, VA: Alvotech USA Inc.; February 2025.
35. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
36. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
37. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; May 2025.
38. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
39. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
40. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; August 2024.
41. Tofidence [package insert]. Cambridge, MA: Biogen MA Inc.; March 2025.
42. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
43. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi, USA LLC; February 2025.
44. Velsipity [package insert]. New York, NY: Pfizer Inc.; June 2024.
45. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer Labs; February 2025.
46. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2024.
47. Yusimry [package insert]. Chicago, IL: Meitheal Pharmaceuticals; September 2023.
48. Zeposia [package insert]. Princeton, NJ: Celgene Corporation; August 2024.
49. Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; July 2024.