AUTOIMMUNE CONDITIONS EXCEPTIONS CRITERIA

PREFERRED PRODUCTS FOR ANKYLOSING SPONDYLITIS: COSENTYX (SC), ENBREL, HUMIRA, AND RINVOQ

PREFERRED PRODUCTS FOR CROHN'S DISEASE: HUMIRA, RINVOQ, SKYRIZI, TREMFYA (IV/SC), AND YESINTEK (IV/SC)

PREFERRED PRODUCTS FOR HIDRADENITIS SUPPURATIVA: COSENTYX (SC), HUMIRA

PREFERRED PRODUCTS FOR PLAQUE PSORIASIS: HUMIRA, OTEZLA/OTEZLA XR, SKYRIZI (SC), TALTZ, TREMFYA (SC), AND YESINTEK (SC)

PREFERRED PRODUCTS FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: ENBREL AND HUMIRA

PREFERRED PRODUCTS FOR PSORIATIC ARTHRITIS: COSENTYX (SC), ENBREL, HUMIRA, OTEZLA/OTEZLA XR, RINVOQ, SKYRIZI (SC), TREMFYA (SC), AND YESINTEK (SC)

PREFERRED PRODUCTS FOR RHEUMATOID ARTHRITIS: ENBREL, HUMIRA, KEVZARA, RINVOQ, AND XELJANZ/XELJANZ XR

PREFERRED PRODUCTS FOR ULCERATIVE COLITIS: HUMIRA, RINVOQ, SKYRIZI (IV/SC), TREMFYA (IV/SC), XELJANZ/XELJANZ XR, AND YESINTEK (IV/SC)

PREFERRED PRODUCTS FOR UVEITIS: HUMIRA

PREFERRED PRODUCTS FOR NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: CIMZIA, COSENTYX (SC), AND RINVOQ

PREFERRED PRODUCTS FOR INFLIXIMAB (ALL INDICATIONS): AVSOLA

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the autoimmune drug products specified in this policy. 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.

- For plaque psoriasis, this program applies to all members requesting treatment with a targeted product.

- For all other indications, this program applies to all members requesting treatment with a targeted product, except where prior use exemptions are noted in the criteria.

Preferred products and targeted products for each indication are listed in Table 1 and Table 2 within this policy. Coverage criteria for targeted products are outlined in Section II. Exception Criteria.

- Each request is reviewed based on all applicable Plan utilization management (UM) programs.
- This exception policy is only one component of the overall UM approach for these medications. Other UM programs, such as medical necessity review or plan quantity limits, may also apply. Please refer to the appropriate utilization management policies for additional criteria that may be required.
- [s] indicates state mandates may apply.

Table 1. Drugs for autoimmune conditions (non-infliximab products)[s]

Indication	Preferred Product*	Targeted Product(s)
Plaque psoriasis	• Humira (adalimumab) • Otezla/Otezla XR (apremilast) • Skyrizi (SC) (risankizumab-rzaa) • Taltz (ixekizumab) • Tremfya (SC) (guselkumab) • Yesintek (SC) (ustekinumab-kfce)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Bimzelx (bimekizumab-bkzx) • Cimzia (certolizumab pegol) • Cosentyx (SC) (secukinumab) • Cyltezo (adalimumab-adbm) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Ilumya (tildrakizumab-asmn) • Imuldosa (SC) (ustekinumab-srlf) • Otulfi (SC) (ustekinumab-aauz) • Pyzchiva (SC) (ustekinumab-ttwe) • Selarsdi (SC) (ustekinumab-aekn) • Siliq (brodalumab) • Simlandi (adalimumab-ryvk) • Sotyktu (deucravacitinib) • Starjemza (SC) (ustekinumab-hmny) • Stelara (SC) (ustekinumab) • Steqeyma (ustekinumab-stba) • ustekinumab-aauz (SC) • ustekinumab-ttwe (SC) • Wezlana (SC) (ustekinumab-auub) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Hidradenitis suppurativa	• Cosentyx (SC) (secukinumab) • Humira (adalimumab)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Bimzelx (bimekizumab-bkzx) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Simlandi (adalimumab-ryvk) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)
Ankylosing spondylitis	• Cosentyx (SC) (secukinumab) • Enbrel (etanercept) • Humira (adalimumab) • Rinvoq (upadacitinib)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Bimzelx (bimekizumab-bkzx) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Taltz (ixekizumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Psoriatic arthritis	• Cosentyx (SC) (secukinumab) • Enbrel (etanercept) • Humira (adalimumab) • Otezla/Otezla XR (apremilast) • Rinvoq (upadacitinib) • Skyrizi (SC) (risankizumab-rzaa) • Tremfya (SC) (guselkumab) • Yesintek (SC) (ustekinumab-kfce)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Bimzelx (bimekizumab-bkzx) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Imuldosa (SC) (ustekinumab-srlf) • Orencia (IV/SC)/Orencia ClickJect (abatacept) • Otulfi (SC) (ustekinumab-aauz) • Pyzchiva (SC) (ustekinumab-ttwe) • Selarsdi (SC) (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Starjemza (SC) (ustekinumab-hmny) • Stelara (SC) (ustekinumab) • Steqeyma (SC) (ustekinumab-stba) • ustekinumab-aauz (SC) • ustekinumab-ttwe (SC) • Taltz (ixekizumab) • Wezlana (SC) (ustekinumab-auub) • Xeljanz/Xeljanz XR (tofacitinib) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Rheumatoid arthritis	• Enbrel (etanercept) • Humira (adalimumab) • Kevzara (sarilumab) • Rinvoq (upadacitinib) • Xeljanz/Xeljanz XR (tofacitinib)	• Abrilada (adalimumab-afzb) • Actemra (IV/SC)/Actemra Actpen (tocilizumab) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Avtozma (IV/SC) (tocilizumab-anoh) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Kineret (anakinra) • Olumiant (baricitinib) • Orencia (IV/SC)/Orencia ClickJect (abatacept) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Tofidence (tocilizumab-bavi) • Tyenne (IV/SC) (tocilizumab-aazg) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Polyarticular juvenile idiopathic arthritis	• Enbrel (etanercept) • Humira (adalimumab)	• Abrilada (adalimumab-afzb) • Actemra (IV/SC)/Actemra Actpen (tocilizumab) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Avtozma (IV/SC) (tocilizumab-anoh) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Orencia (IV/SC)/Orencia ClickJect (abatacept) • Rinvoq (upadacitinib)† †See section I.G.5 • Simlandi (adalimumab-ryvk) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)
Uveitis	• Humira (adalimumab)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Simlandi (adalimumab-ryvk) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Crohn's disease	• Humira (adalimumab) • Rinvoq (upadacitinib) • Skyrizi (IV/SC) (risankizumab-rzaa) • Tremfya (IV/SC) (guselkumab) • Yesintek (IV/SC) (ustekinumab-kfce)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Entyvio (IV/SC) (vedolizumab) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Imuldosa (IV/SC) (ustekinumab-srlf) • Omvoh (IV/SC) (mirikizumab-mrkz) • Otulfi (IV/SC) (ustekinumab-aauz) • Pyzchiva (IV/SC) (ustekinumab-ttwe) • Selarsdi (IV/SC) (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Starjemza (IV/SC) (ustekinumab-hmny) • Stelara (IV/SC) (ustekinumab) • Steqeyma (IV/SC) (ustekinumab-stba) • ustekinumab-aauz (SC) • ustekinumab-ttwe (IV/SC) • Wezlana (IV/SC) (ustekinumab-auub) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Ulcerative colitis	• Humira (adalimumab) • Rinvoq (upadacitinib) • Skyrizi (IV/SC) (risankizumab-rzaa) • Tremfya (IV/SC) (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib)† †See section I.F.1 • Yesintek (IV/SC) (ustekinumab-kfce)	• Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Cyltezo (adalimumab-adbm) • Entyvio (IV/SC) (vedolizumab)† †See section I.F.4 • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Imuldosa (IV/SC) (ustekinumab-srlf) • Omvoh (IV/SC) (mirikizumab-mrkz) • Otulfi (IV/SC) (ustekinumab-aauz) • Pyzchiva (IV/SC) (ustekinumab-ttwe) • Selarsdi (IV/SC) (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Starjemza (IV/SC) (ustekinumab-hmny) • Stelara (IV/SC) (ustekinumab) • Steqeyma (IV/SC) (ustekinumab-stba) • ustekinumab-aauz (SC) • ustekinumab-ttwe (IV/SC) • Velsipity (etrasimod) • Wezlana (IV/SC) (ustekinumab-auub) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh) • Zeposia (ozanimod)
Non-Radiographic Axial Spondyloarthritis	• Cimzia (certolizumab pegol) • Cosentyx (SC) (secukinumab) • Rinvoq (upadacitinib)	• Bimzelx (bimekizumab-bkzx) • Taltz (ixekizumab)

Abbreviations: IV = intravenous, SC = subcutaneous

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

Table 2. Infliximab Products[s]

Indication	Preferred Product*	Targeted Product(s)
All Indications	• Avsola (infliximab-axxq)	• Inflectra (infliximab-dyyb) • Infliximab • Remicade (infliximab) • Renflexis (infliximab-abda) • Zymfentra (infliximab-dyyb)

I. EXCEPTION CRITERIA[s]

Coverage for a targeted product listed in Table 1 (non-infliximab products) is provided when ONE of the following criteria is met:

A. Ankylosing spondylitis and the member meets ONE of the following criteria:
   1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Cosentyx SC, Enbrel, Humira, and Rinvoq). 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 product(s) from the respective class*; OR*
   2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
      a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
      b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Cosentyx SC, Enbrel, and Rinvoq), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B)*; OR*
   3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*
   4. The requested product is Bimzelx, Cimzia, Simponi, Taltz, 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*; OR*

B. Crohn's disease and the member meets ONE of the following criteria:
   1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, Tremfya IV/SC, and Yesintek 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 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*; OR*
   2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
      a. Member has had a documented intolerable adverse event to Humira, 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); and
      b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Rinvoq, Skyrizi IV/SC, Tremfya IV/SC, and Yesintek IV/SC). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B), or is a 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*; OR*
   3. The requested product is a targeted ustekinumab product, and the member meets BOTH of the following:
      a. Member has had a documented intolerable adverse event to the preferred ustekinumab product (Yesintek IV/SC), 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)*; and*
      b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, and Tremfya IV/SC). 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 product(s) from the respective class*; OR*

4. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*
5. The requested product is Entyvio SC and the member received Entyvio IV for induction therapy*; OR*
6. The requested product is Omvoh SC and the member received Omvoh IV for induction therapy*; OR*
7. The requested product is Cimzia, Entyvio IV/SC, Omvoh IV/SC, or ustekinumab biosimilar 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*; OR*

C. Plaque psoriasis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Otezla/Otezla XR, Skyrizi SC, Taltz, Tremfya SC, and Yesintek SC), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A)*; OR*
2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
   a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
   b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Otezla/Otezla XR, Skyrizi SC, Taltz, Tremfya SC, and Yesintek SC)*; OR*
3. The requested product is a targeted ustekinumab product, and the member meets BOTH of the following:
   a. Member has had a documented intolerable adverse event to the preferred ustekinumab product (Yesintek SC), 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)*; and*
   b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Otezla/Otezla XR, Skyrizi SC, Taltz, and Tremfya SC). 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 product(s) from the respective class*; OR*
4. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*
5. The requested product is an ustekinumab biosimilar 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*; OR*

D. Psoriatic arthritis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with at least SIX of the preferred products (Cosentyx SC, Enbrel, Humira, Otezla/Otezla XR, Rinvoq, Skyrizi SC, Tremfya SC, and/or Yesintek SC). 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 product(s) from the respective class*; OR*
2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:

a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
b. Member has a documented inadequate response or intolerable adverse event with at least FIVE of the preferred products (Cosentyx SC, Enbrel, Otezla/Otezla XR, Rinvoq, Skyrizi SC, Tremfya SC, and/or Yesintek SC), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B)*; OR*

3. The requested product is a targeted ustekinumab product, and the member meets BOTH of the following:
   a. Member has had a documented intolerable adverse event to the preferred ustekinumab product (Yesintek SC), 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)*; and*
   b. Member has a documented inadequate response or intolerable adverse event with at least FIVE of the preferred products (Cosentyx SC, Enbrel, Humira, Otezla/Otezla XR, Rinvoq, Skyrizi SC, and/or Tremfya SC), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A)*; OR*
4. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*
5. The requested product is Bimzelx, Cimzia, Orencia IV/SC/Orencia ClickJect, Simponi, ustekinumab biosimilar SC, Taltz, 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*; OR*

E. Rheumatoid arthritis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Enbrel, Humira, Kevzara, Rinvoq, and Xeljanz/Xeljanz XR). 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 product(s) from the respective class*; OR*
2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
   a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
   b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Enbrel, Kevzara, Rinvoq, and Xeljanz/Xeljanz XR), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B)*; OR*
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*
4. The requested product is Actemra IV/SC/Actemra ACTPen, Avtozma IV/SC, Cimzia, Kineret, Olumiant, Orencia IV/SC/Orencia ClickJect, Simponi, Tofidence, or Tyenne 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*; OR*

F. Ulcerative colitis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, Tremfya IV/SC, Xeljanz/Xeljanz XR, and Yesintek IV/SC). Additionally, if the request is for Xeljanz/Xeljanz XR, the member has had a documented inadequate

response or intolerable adverse event with any ONE TNF inhibitor. If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see Appendix B), or is a 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*; OR*

2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
    a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
    b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Rinvoq, Skyrizi IV/SC, Tremfya IV/SC, Xeljanz/Xeljanz XR, and Yesintek IV/SC). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B), or is a 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*; OR*
3. The requested product is a targeted ustekinumab product, and the member meets BOTH of the following:
    a. Member has had a documented intolerable adverse event to the preferred ustekinumab product (Yesintek IV/SC), 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)*; and*
    b. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, Tremfya IV/SC, and Xeljanz/Xeljanz XR,). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see Appendix B), or is a 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*; OR*.
4. The requested product is for Entyvio IV*; OR*
5. The requested product is for Entyvio SC and the member received Entyvio IV for induction therapy*; OR*
6. The requested product is for Omvoh SC and the member received Omvoh IV for induction therapy*; OR*
7. The requested product is Entyvio SC, Omvoh IV/SC, Simponi, ustekinumab IV/SC biosimilar, Velsipity, 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*; OR*

G. Polyarticular juvenile idiopathic arthritis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with BOTH of the preferred products (Enbrel and Humira), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A)*; OR*
2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
    a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
    b. Member has a documented inadequate response or intolerable adverse event with the preferred product, Enbrel*; OR*
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy*; OR*

4. The requested product is Actemra IV/SC/Actemra ACTPen, Avtozma IV/SC, Cimzia, or Orencia IV/SC/Orencia ClickJect, 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*; OR*
5. The requested product is Rinvoq, and the member has a documented inadequate response or intolerance to any ONE TNF inhibitor*; OR*

H. Hidradenitis suppurativa and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with BOTH of the preferred products (Cosentyx SC or Humira), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A)*; OR*
2. The requested product is a targeted adalimumab product, and the member meets BOTH of the following:
   a. Member has had a documented intolerable adverse event to Humira, 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)*; and*
   b. Member has a documented inadequate response or intolerable adverse event with the preferred product, Cosentyx (SC)*; OR*
3. The requested product is Bimzelx, 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*; OR*

I. Uveitis and the member meets the following criterion:
1. Member has had a documented intolerable adverse event to Humira, 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).

J. Non-Radiographic Axial Spondyloarthritis and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with ALL of the preferred products (Cimzia, Cosentyx SC, and Rinvoq). 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*; OR*
2. Member is currently receiving treatment with the requested targeted product (Bimzelx or Taltz), excluding when it is obtained as samples or via manufacturer's patient assistance programs.

For infliximab products listed in Table 2, coverage for a targeted product is provided when ONE of the following criteria is met:

K. Infliximab Products – All Indications and the member meets ONE of the following criteria:
1. Member has a documented inadequate response or intolerable adverse event with Avsola (infliximab-axxq), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information*; OR*
2. The prescriber provides a documented clinical reason why Avsola cannot be used, such as a history of severe hypersensitivity reaction to specific inactive ingredients present in Avsola but not in the requested product*; OR*
3. The member is currently stable on the requested infliximab product, and the prescriber provides documentation that switching to Avsola would pose a significant risk of destabilizing the member's condition. This could include, but is not limited to:
   a. Members with a history of secondary loss of response after switching between infliximab products*; or*
   b. Members with complex disease states where maintaining the current regimen is deemed critical for disease control*; OR*

4. The requested product is Zymfentra, and the member has undergone induction with infliximab (any brand) and the prescriber deems it clinically appropriate to continue maintenance therapy with Zymfentra.

II. APPENDICES

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

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