

EXCEPTIONS CRITERIA AUTOIMMUNE CONDITIONS

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

PREFERRED PRODUCTS FOR CROHN'S DISEASE: HUMIRA, RINVOQ, SKYRIZI, STELARA, AND TREMFYA

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

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

PREFERRED PRODUCTS FOR POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: ENBREL AND HUMIRA

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

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

PREFERRED PRODUCTS FOR ULCERATIVE COLITIS: HUMIRA, RINVOQ, SKYRIZI, STELARA, TREMFYA, AND XELJANZ/XELJANZ XR

PREFERRED PRODUCTS FOR UVEITIS: HUMIRA

PREFERRED PRODUCTS FOR INFILIXIMAB (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.

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

Indication	Preferred Product*	Targeted Product(s)
Plaque psoriasis	<ul style="list-style-type: none"> • Humira (adalimumab) • Otezla (apremilast) • Skyrizi (SC) (risankizumab-rzaa) • Stelara (SC) (ustekinumab) • Taltz (ixekizumab) • Tremfya (guselkumab) 	<ul style="list-style-type: none"> • 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) • Imuldos (ustekinumab-srlf) • Otulfi (ustekinumab-aauz) • Pyzchiva (ustekinumab-ttwe) • Selarsdi (ustekinumab-aekn) • Siliq (brodalumab) • Simlandi (adalimumab-ryvk) • Sotyktu (deucravacitinib) • Starjema (ustekinumab-hmny) • Steqeyma (ustekinumab-stba) • Wezlana (ustekinumab-aaub) • Yesintek (ustekinumab-kfce) • Yufluma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)
Hidradenitis suppurativa	<ul style="list-style-type: none"> • Cosentyx (SC) (secukinumab) • Humira (adalimumab) 	<ul style="list-style-type: none"> • 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) • Yufluma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Ankylosing spondylitis	<ul style="list-style-type: none"> Cosentyx (SC) (secukinumab) Enbrel (etanercept) Humira (adalimumab) Rinvoq (upadacitinib) 	<ul style="list-style-type: none"> 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)
Psoriatic arthritis	<ul style="list-style-type: none"> Cosentyx (SC) (secukinumab) Enbrel (etanercept) Humira (adalimumab) Otezla (apremilast) Rinvoq (upadacitinib) Skyrizi (SC) (risankizumab-rzaa) Tremfya (guselkumab) 	<ul style="list-style-type: none"> 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 (ustekinumab-srlf) Orencia (IV/SC)/Orencia ClickJect (abatacept) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Selarsdi (ustekinumab-aekn) Simlandi (adalimumab-ryvk) Simponi (golimumab) Starjemza (ustekinumab-hmny) Stelara (SC) (ustekinumab) Steqeyma (ustekinumab-stba) Taltz (ixekizumab) Wezlana (ustekinumab-aaub) Xeljanz/Xeljanz XR (tofacitinib) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh)

Indication	Preferred Product*	Targeted Product(s)
Rheumatoid arthritis	<ul style="list-style-type: none"> • Enbrel (etanercept) • Humira (adalimumab) • Kevzara (sarilumab) • Rinvoq (upadacitinib) • Xeljanz/Xeljanz XR (tofacitinib) 	<ul style="list-style-type: none"> • Abrilada (adalimumab-afzb) • Actemra (IV/SC)/Actemra Actpen (tocilizumab) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • 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) • Tofidience (tocilizumab-bavi) • Tyenne (tocilizumab-aazg) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)
Polyarticular juvenile idiopathic arthritis	<ul style="list-style-type: none"> • Enbrel (etanercept) • Humira (adalimumab) 	<ul style="list-style-type: none"> • Abrilada (adalimumab-afzb) • Actemra (IV/SC)/Actemra Actpen (tocilizumab) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk • Amjevita (adalimumab-atto) • Cimzia (certolizumab pegol) • Cyltezo (adalimumab-adbm) • Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Orencia (IV/SC)/Orencia ClickJect (abatacept) • Simlandi (adalimumab-ryvk) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh)
Uveitis	<ul style="list-style-type: none"> • Humira (adalimumab) 	<ul style="list-style-type: none"> • Abrilada (adalimumab-afzb) • adalimumab-aacf • adalimumab-aaty • adalimumab-adaz • adalimumab-adbm • adalimumab-fkjp • adalimumab-ryvk

Indication	Preferred Product*	Targeted Product(s)
		<ul style="list-style-type: none"> 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)
Crohn's disease	<ul style="list-style-type: none"> Humira (adalimumab) Rinvoq (upadacitinib) Skyrizi (IV/SC) (risankizumab-rzaa) Stelara (IV/SC) (ustekinumab) Tremfya (guselkumab) 	<ul style="list-style-type: none"> 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 (ustekinumab-srlf) Omvoh (IV/SC) (mirikizumab-mrkz) Otulifi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Selarsdi (ustekinumab-aekn) Simlandi (adalimumab-ryvk) Starjemza (ustekinumab-hmny) Steqeyma (ustekinumab-stba) Wezlana (ustekinumab-aaub) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh)
Ulcerative colitis	<ul style="list-style-type: none"> Humira (adalimumab) Rinvoq (upadacitinib) Skyrizi (IV/SC) (risankizumab-rzaa) Stelara (IV/SC) (ustekinumab) Tremfya (guselkumab) Xeljanz/Xeljanz XR (tofacitinib) 	<ul style="list-style-type: none"> 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.3 Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Imuldosa (ustekinumab-srlf) Omvoh (IV/SC) (mirikizumab-mrkz)

Indication	Preferred Product*	Targeted Product(s)
		<ul style="list-style-type: none"> • Otulfi (ustekinumab-aauz) • Pyzchiva (ustekinumab-ttwe) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) • Starjemza (ustekinumab-hmny) • Steqeyma (ustekinumab-stba) • Velsipipty (etrasimod) • Wezlana (ustekinumab-aaub) • Yesintek (ustekinumab-kfce) • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh) • Zeposia (ozanimod)

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

Indication	Preferred Product*	Targeted Product(s)
All Indications	<ul style="list-style-type: none"> • Avsola (infliximab-axxq) 	<ul style="list-style-type: none"> • Inflectra (infliximab-dyyb) • Infliximab • Remicade (infliximab) • Renflexis (infliximab-abda) • Zymfentra (infliximab-dyyb)

I. EXCEPTION CRITERIA

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

A. Ankylosing spondylitis

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.
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).
 - 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).
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
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.

B. Crohn's disease

1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, Stelara IV/SC, and Tremfya). 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.

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).
 - b. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Rinvoq, Skyrizi IV/SC, Stelara IV/SC, and Tremfya). 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.
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
4. The requested product is Cimzia, Entyvio IV/SC, Omvoh IV/SC, or ustekinumab biosimilar, 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.

C. Plaque psoriasis

1. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
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).
 - b. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya).
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
4. The requested product is an ustekinumab biosimilar, 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.

D. Psoriatic arthritis

1. Member has a documented inadequate response or intolerable adverse event with at least six of the preferred products (Cosentyx SC, Enbrel, Humira, Otezla, Rinvoq, Skyrizi SC, Tremfya). 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.
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).
 - b. Member has a documented inadequate response or intolerable adverse event with at least five of the preferred products (Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC, Tremfya), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
4. The requested product is Bimzelx, Cimzia, Orencia IV/SC/Orencia ClickJect, Simponi, Stelara SC, ustekinumab biosimilar, 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.

E. Rheumatoid arthritis

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.
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).
 - 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).
3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
4. The requested product is Actemra, Cimzia, Kineret, Olumiant, Orencia IV/SC/Orencia ClickJect, Simponi, Tofidience, or Tyenne, 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.

F. Ulcerative colitis

1. Member has had a documented inadequate response or intolerable adverse event with all of the preferred products (Humira, Rinvoq, Skyrizi IV/SC, Stelara IV/SC, Tremfya, and Xeljanz/Xeljanz XR). Additionally, if the request is for Xeljanz/Xeljanz XR, the member has had a documented inadequate response or intolerable adverse event with Humira. 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.
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).
 - b. Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Rinvoq, Skyrizi IV/SC, Stelara IV/SC, Tremfya, and Xeljanz/Xeljanz XR). 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.
3. The requested product is Entyvio IV.
4. The requested product is Entyvio SC, Omvoh IV/SC, Simponi, ustekinumab 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.

G. Polyarticular juvenile idiopathic arthritis

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).
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).

- b. Member has a documented inadequate response or intolerable adverse event with the preferred product, Enbrel.
- 3. The requested product is Cimzia, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- 4. The requested product is Actemra, 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.

H. Hidradenitis suppurativa

1. The requested product is Bimzelx (bimekizumab-bkzx), and the member has a documented inadequate response or intolerable adverse event with BOTH preferred products Humira and Cosentyx (SC).
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).
 - b. Member has a documented inadequate response or intolerable adverse event with the preferred product, Cosentyx (SC).

I. Uveitis

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).

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

J. Infliximab Products – All Indications

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.
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.
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.
 - b. Members with complex disease states where maintaining the current regimen is deemed critical for disease control.
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

REFERENCES

1. Abrilada [package insert]. New York, NY: Pfizer Inc.; April 2024.
2. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
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.; December 2023.
5. adalimumab-adaz [package insert]. Princeton, NJ: Sandoz Inc.; June 2024.
6. adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
7. adalimumab-fkjp [package insert]. Morgantown, WV: Mylan Specialty L.P.; December 2023.
8. adalimumab-ryvk [package insert]. Leesburg, VA: Alvotech USA Inc.; May 2024.
9. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2023.
10. Avsola [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
11. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; October 2023.
12. Bimzelx (bimekizumab) [prescribing information]. Smyrna, GA: UCB Inc; November 2024.
13. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; December 2022.
14. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023.
15. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
16. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; October 2023.
17. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; April 2024.
18. Hadlima [package insert]. Jersey City, NJ: Organon LLC; June 2024.
19. Hulio [package insert]. Morgantown, WV: Mylan Specialty L.P.; August 2023.
20. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
21. Hyrimoz [package insert]. Princeton, NJ: Sandoz Inc.; April 2024.
22. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; January 2024.
23. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
24. Imuldosa (ustekinumab) [prescribing information]. Raleigh, NC: Accord BioPharma Inc; October 2024.
25. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
26. Kevzara [package insert]. Bridgewater, NJ: Sanofi-aventis, U.S. LLC/Regeneron Pharmaceuticals, Inc.; June 2024.
27. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.
28. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
29. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2024.
30. Omvoh (mirikizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; January 2025.
31. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; May 2024.
32. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
33. Otulifi (ustekinumab) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; March 2025.
34. Pyzchiva (ustekinumab) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2025.
35. Renflexis [package insert]. Jersey City, NJ. Organon & Co.; December 2023.
36. Rinvoq [package insert]. North Chicago, IL; AbbVie, Inc.; April 2024.
37. Selarsdi (ustekinumab) [prescribing information]. Leesburg, VA: Alvotech USA Inc; February 2025.
38. Siliq [package insert]. Bridgewater, NJ: Bausch Health US, LLC; July 2024.
39. Simlandi [package insert]. Leesburg, VA: Alvotech USA Inc.; June 2024.
40. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
41. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
42. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
43. Starjemza (ustekinumab) [prescribing information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc; May 2025.

44. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2022.
45. Steqeyma (ustekinumab) [prescribing information]. Jersey City, NJ: Celltrion USA Inc; February 2025.
46. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2024.
47. Tofidience [package insert]. Cambridge, MA: Biogen MA Inc.; September 2023.
48. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2023.
49. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC; March 2024.
50. Velsipity [package insert]. New York, NY: Pfizer Inc.; June 2024.
51. Wezlana (ustekinumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2025.
52. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; May 2024.
53. Yesintek (ustekinumab) [prescribing information]. Cambridge, MA: Biocon Biologics Inc; November 2024.
54. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2024.
55. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2023.
56. Zeposia [package insert]. Summit, NJ: Celgene Corporation; August 2023.
57. Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2024.