

Reference number(s) 4250-D

#### This document applies to the following:

Formulary	Applies
Standard Control (SF)	
Standard Control – Choice (SCCF)	
Preferred Drug Plan Design (PDPD)	$\checkmark$
Advanced Control Specialty (ACSF)	V
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: Preferred Drug Plan Design (PDPD) and Advanced Control Specialty Formulary (ACSF).

## **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 alopecia areata and plaque psoriasis, all members requesting treatment with a non-primary preferred product.
- For non-radiographic axial spondyloarthritis, all members who are new to treatment with a targeted product for the first time.
- For all other indications, all members requesting treatment with Abrilada, adalimumab-aacf, adalimumab-aaty, adalimumab-adbm, adalimumab-ryvk, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz (Sandoz), Idacio, Imuldosa, Inflectra, infliximab, Otulfi, Renflexis, Selarsdi, Simlandi, Steqeyma, ustekinumab-ttwe, Wezlana, Yuflyma, Yusimry, and Zymfentra, and all members who are new to treatment with all other non-primary preferred products for the first time.

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

### Table 1. Self-Administered Drugs for Autoimmune Conditions

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

Abbreviation: SC = subcutaneous Indication: Plaque Psoriasis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Bimzelx (bimekizumab-bkzx)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Otezla (apremilast)</li> <li>Pyzchiva (SC) (ustekinumab- ttwe)</li> <li>Skyrizi (SC) (risankizumab- rzaa)</li> <li>Sotyktu (deucravacitinib)</li> <li>Stelara (SC) (ustekinumab)</li> <li>Tremfya (SC) (guselkumab)</li> <li>Yesintek (SC) (ustekinumab- kfce)</li> </ul>	<ul> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cosentyx (SC) (secukinumab)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Enbrel (etanercept)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Imuldosa (SC) (ustekinumab- srlf)</li> <li>Otulfi (SC) (ustekinumab- aekn)</li> <li>Siliq (brodalumab)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Steqeyma (SC) (ustekinumab- stba)</li> <li>Taltz (ixekizumab)</li> <li>Ustekinumab-ttwe (SC)</li> <li>Wezlana (SC) (ustekinumab- auub)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> </ul>

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Indication: Hidradenitis Suppurativa

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Cosentyx (SC) (secukinumab)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> </ul>	• None	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Bimzelx (bimekizumab-bkzx)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Yuflyma (adalimumab-aqvh)</li> </ul>

#### Indication: Ankylosing Spondylitis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Cosentyx (SC) (secukinumab)</li> <li>Enbrel (etanercept)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Rinvoq (upadacitinib)</li> </ul>	<ul> <li>Bimzelx (bimekizumab- bkzx) (after 2 primary preferred products)</li> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Simponi (golimumab)</li> <li>Taltz (ixekizumab)</li> </ul>

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Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
		<ul> <li>Xeljanz/Xeljanz XR (tofacitinib)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> </ul>

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#### Indication: Psoriatic Arthritis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Cosentyx (SC) (secukinumab)</li> <li>Enbrel (etanercept)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Otezla (apremilast)</li> <li>Pyzchiva (SC) (ustekinumab- ttwe)</li> <li>Rinvoq (upadacitinib)</li> <li>Skyrizi (SC) (risankizumab- rzaa)</li> <li>Stelara (SC) (ustekinumab)</li> <li>Tremfya (SC) (guselkumab)</li> <li>Yesintek (SC) (ustekinumab- kfce)</li> </ul>	<ul> <li>Bimzelx (bimekizumab- bkzx) (after 2 primary preferred products)</li> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hudio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Imuldosa (SC) (ustekinumab- srlf)</li> <li>Orencia (SC)/Orencia ClickJect (abatacept)</li> <li>Otulfi (SC) (ustekinumab- aauz)</li> <li>Selarsdi (SC) (ustekinumab- aekn)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Simponi (golimumab)</li> <li>Steqeyma (SC) (ustekinumab- stba)</li> <li>Taltz (ixekizumab)</li> <li>ustekinumab-ttwe (SC)</li> <li>Wezlana (SC) (ustekinumab- auub)</li> <li>Xeljanz/Xeljanz XR (tofacitinib)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> </ul>

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#### Indication: Rheumatoid Arthritis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Enbrel (etanercept)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Kevzara (sarilumab)</li> <li>Orencia (SC)/Orencia ClickJect (abatacept)</li> <li>Rinvoq (upadacitinib)</li> <li>Xeljanz/Xeljanz XR (tofacitinib)</li> </ul>	<ul> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>Actemra (SC)/Actemra Actpen (tocilizumab)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Kineret (anakinra)</li> <li>Olumiant (baricitinib)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Simponi (golimumab)</li> <li>Tyenne (SC) (tocilizumab-aazy)</li> <li>Yuflyma (adalimumab-aqvh)</li> </ul>

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#### Indication: Non-Radiographic Axial Spondyloarthritis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>Cimzia syringe (certolizumab pegol)</li> <li>Cosentyx (SC) (secukinumab)</li> <li>Rinvoq (upadacitinib)</li> </ul>	• None	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adaz</li> <li>adalimumab-adbm</li> <li>adalimumab-fkjp</li> <li>adalimumab-fkjp</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Bimzelx (bimekizumab-bkzx)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Enbrel (etanercept)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab-adaz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Simlandi (adalimumab-aacf)</li> <li>Taltz (ixekizumab)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> </ul>

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Indication: Polyarticular Juvenile Idiopathic Arthritis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Enbrel (etanercept)</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> </ul>	<ul> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>Actemra (SC)/Actemra Actpen (tocilizumab)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Orencia (SC)/Orencia ClickJect (abatacept)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Tyenne (SC) (tocilizumab- aazg)</li> <li>Yuflyma (adalimumab-aaqvh)</li> </ul>

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#### Indication: Uveitis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> </ul>	• None	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Hadlima (adalimumab-adbm)</li> <li>Hudlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Simlandi (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> </ul>

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#### Indication: Crohn's Disease

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Pyzchiva (SC) (ustekinumab- ttwe)</li> <li>Rinvoq (upadacitinib)</li> <li>Skyrizi (SC) (risankizumab- rzaa)</li> <li>Stelara (SC) (ustekinumab)</li> <li>Tremfya (SC) (guselkumab)</li> <li>Yesintek (SC) (ustekinumab- kfce)</li> </ul>	<ul> <li>Cimzia syringe (certolizumab pegol) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Entyvio (SC) (vedolizumab)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Imuldosa (SC) (ustekinumab- srlf)</li> <li>Omvoh (SC) (mirikizumab- mrkz)</li> <li>Otulfi (SC) (ustekinumab- aauz)</li> <li>Selarsdi (SC) (ustekinumab- aekn)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Steqeyma (SC) (ustekinumab- stba)</li> <li>ustekinumab-ttwe (SC)</li> <li>Wezlana (SC) (ustekinumab- auub)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> <li>Zymfentra (infliximab-dyyb)</li> </ul>

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#### Indication: Ulcerative Colitis

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
<ul> <li>adalimumab-adaz</li> <li>adalimumab-fkjp</li> <li>Hyrimoz (adalimumab-adaz) (Cordavis)</li> <li>Pyzchiva (SC) (ustekinumab- ttwe)</li> <li>Rinvoq (upadacitinib)</li> <li>Skyrizi (SC) (risankizumab- rzaa)</li> <li>Stelara (SC) (ustekinumab)</li> <li>Tremfya (SC) (guselkumab)</li> <li>Velsipity (etrasimod)</li> <li>Yesintek (SC) (ustekinumab- kfce)</li> <li>Zeposia (ozanimod)</li> </ul>	<ul> <li>Xeljanz/Xeljanz XR (tofacitinib) (after 2 primary preferred products)</li> </ul>	<ul> <li>Abrilada (adalimumab-afzb)</li> <li>adalimumab-aacf</li> <li>adalimumab-aaty</li> <li>adalimumab-adbm</li> <li>adalimumab-ryvk</li> <li>Amjevita (adalimumab-atto)</li> <li>Cyltezo (adalimumab-adbm)</li> <li>Entyvio (SC) (vedolizumab)</li> <li>Hadlima (adalimumab-bwwd)</li> <li>Hulio (adalimumab-fkjp)</li> <li>Humira (adalimumab)</li> <li>Hyrimoz (adalimumab-adaz) (Sandoz)</li> <li>Idacio (adalimumab-aacf)</li> <li>Imuldosa (SC) (ustekinumab- srlf)</li> <li>Otulfi (SC) (ustekinumab- aauz)</li> <li>Selarsdi (SC) (ustekinumab- aekn)</li> <li>Simlandi (adalimumab-ryvk)</li> <li>Simponi (golimumab)</li> <li>Steqeyma (SC) (ustekinumab- stba)</li> <li>ustekinumab-ttwe (SC)</li> <li>Wezlana (SC) (ustekinumab- auub)</li> <li>Yuflyma (adalimumab-aaty)</li> <li>Yusimry (adalimumab-aqvh)</li> <li>Zymfentra (infliximab-dyyb)</li> </ul>

#### Indication: Alopecia Areata

Primary Preferred Product(s)	Secondary Preferred Product(s)	Targeted Product(s)
Litfulo (ritlecitinib)	None	Olumiant (baricitinib)

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### Table 2. Physician-Administered Drugs for Autoimmune Conditions

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

Abbreviation: IV = i	ntravenous
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Preferred Product(s)	Targeted Product(s)
<ul> <li>Avsola (infliximab-axxq)</li> <li>Remicade (infliximab)</li> <li>Simponi Aria (golimumab)</li> </ul>	<ul> <li>Actemra (IV) (tocilizumab)</li> <li>Cimzia lyophilized powder (certolizumab pegol)</li> <li>Cosentyx (IV) (secukinumab)</li> <li>Inflectra (infliximab-dyyb)</li> <li>infliximab</li> <li>Orencia (IV) (abatacept)</li> <li>Renflexis (infliximab-abda)</li> <li>Tofidence (IV) (tocilizumab-bavi)</li> <li>Tyenne (IV) (tocilizumab-aazg)</li> </ul>
<ul> <li>Avsola (infliximab-axxq)</li> <li>Ilumya (tildrakizumab-asmn)</li> <li>Remicade (infliximab)</li> </ul>	<ul> <li>Cimzia lyophilized powder (certolizumab pegol)</li> <li>Inflectra (infliximab-dyyb)</li> <li>infliximab</li> <li>Renflexis (infliximab-abda)</li> </ul>
<ul> <li>Avsola (infliximab-axxq)</li> <li>Pyzchiva (IV) (ustekinumab-ttwe)</li> <li>Remicade (infliximab)</li> <li>Skyrizi (IV) (risankizumab-rzaa)</li> <li>Stelara (IV) (ustekinumab)</li> <li>Tremfya (IV) (guselkumab)</li> <li>Yesintek (IV) (ustekinumab-kfce)</li> </ul>	<ul> <li>Cimzia lyophilized powder (certolizumab pegol)</li> <li>Entyvio (IV) (vedolizumab)</li> <li>Imuldosa (IV) (ustekinumab-srlf)</li> <li>Inflectra (infliximab-dyyb)</li> <li>infliximab</li> <li>Omvoh (IV) (mirikizumab-mrkz)</li> <li>Otulfi (IV) (ustekinumab-aauz)</li> <li>Renflexis (infliximab-abda)</li> <li>Selarsdi (IV) (ustekinumab-aekn)</li> <li>Steqeyma (IV) (ustekinumab-stba)</li> <li>ustekinumab-ttwe (IV)</li> <li>Wezlana (IV) (ustekinumab-auub)</li> </ul>

## **Exception Criteria for Self-Administered Products**

Coverage for a self-administered targeted product, see Table 1 above, is provided when any of the following criteria is met:

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### Ankylosing Spondylitis

- Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Cosentyx SC, Enbrel, and Rinvoq) and both of the secondary preferred products (Bimzelx and Cimzia syringe). If the member has a documented clinical reason to avoid tumor necrosis factor (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 adalimumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 primary preferred products (Cosentyx SC, Enbrel, and Rinvoq) and both of the secondary preferred products (Bimzelx and Cimzia syringe), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
- The requested product is Cimzia syringe, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- The requested product is Bimzelx or Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Cosentyx SC, Enbrel, Hyrimoz, 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.
- The requested product is Bimzelx, Cimzia syringe, 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.

### Crohn's Disease

• Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Rinvoq, Skyrizi SC, Tremfya SC, and an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC]) and the secondary preferred product (Cimzia syringe). 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 products from the respective class.

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- 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 both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 primary preferred products (Rinvoq, Skyrizi SC, Tremfya SC, and an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC]) and the secondary preferred product (Cimzia syringe). 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 ustekinumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to all of the primary preferred ustekinumab products (Pyzchiva SC, Stelara SC, and 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).
  - Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Rinvoq, Skyrizi SC, and Tremfya SC) and the secondary preferred product (Cimzia syringe). 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 Cimzia syringe, 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 Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Hyrimoz, Pyzchiva SC, Rinvoq, Skyrizi SC, Stelara SC, Tremfya SC, Yesintek 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 syringe, Entyvio SC, or Omvoh 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.

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### **Psoriatic Arthritis**

- Member has a documented inadequate response or intolerable adverse event with at least nine of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Bimzelx, Cimzia syringe, Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC, Tremfya SC, an ustekinumab product [Pyzchiva SC, Stelara SC, 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 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 both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 eight of the preferred products (Bimzelx, Cimzia syringe, Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC, Tremfya SC, an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC]), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
- The requested product is a targeted ustekinumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to all of the primary preferred ustekinumab products (Pyzchiva SC, Stelara SC, and 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).
  - Member has a documented inadequate response or intolerable adverse event with at least eight of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Bimzelx, Cimzia syringe, Cosentyx SC, Enbrel, Otezla, Rinvoq, Skyrizi SC, 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 products from the respective class.
- The requested product is Cimzia syringe, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- The requested product is Bimzelx or Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Cosentyx SC, Enbrel, Hyrimoz, Otezla, Pyzchiva SC, Rinvoq, Skyrizi SC, Stelara SC, Tremfya SC, Yesintek SC).

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• The requested product is Bimzelx, Cimzia syringe, Orencia SC/Orencia ClickJect, 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.

### **Plaque Psoriasis**

- Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Bimzelx, Otezla, Skyrizi SC, Sotyktu, Tremfya SC, and an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC]) and the secondary preferred product (Cimzia syringe), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
- 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 both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 primary preferred products (Bimzelx, Otezla, Skyrizi SC, Sotyktu, Tremfya SC, and an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC]) and the secondary preferred product (Cimzia syringe).
- The requested product is a targeted ustekinumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to all of the primary preferred ustekinumab products (Pyzchiva SC, Stelara SC, and 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).
  - Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Bimzelx, Otezla, Skyrizi SC, Sotyktu, and Tremfya SC) and the secondary preferred product (Cimzia syringe), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
- The requested product is Cimzia syringe, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- The requested product is Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Bimzelx, Hyrimoz, Otezla, Pyzchiva SC, Skyrizi SC, Sotyktu, Stelara SC, Tremfya SC, Yesintek SC).

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### **Rheumatoid Arthritis**

- Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Enbrel, Kevzara, Orencia SC/Orencia ClickJect, Rinvoq, and Xeljanz/Xeljanz XR) and the secondary preferred product (Cimzia syringe). 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 adalimumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 primary preferred products (Enbrel, Kevzara, Orencia SC/Orencia ClickJect, Rinvoq, and Xeljanz/Xeljanz XR) and the secondary preferred product (Cimzia syringe), unless there is a documented clinical reason to avoid JAK inhibitors (see Appendix B).
- The requested product is Cimzia syringe, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- The requested product is Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Enbrel, Hyrimoz, Kevzara, Orencia SC/Orencia ClickJect, Rinvoq, Xeljanz/Xeljanz XR).
- The requested product is Actemra SC/Actemra Actpen, Cimzia syringe, Kineret, Olumiant, Simponi, or Tyenne 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**

- Member has had a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Rinvoq, Skyrizi SC, Tremfya SC, an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC], Velsipity, and Zeposia) and the secondary preferred product (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 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:

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- Member has had a documented intolerable adverse event to both of the primary
  preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
  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 primary preferred products (Rinvoq, Skyrizi SC, Tremfya SC, an ustekinumab product [Pyzchiva SC, Stelara SC, or Yesintek SC], Velsipity, and Zeposia) and the secondary preferred product (Xeljanz/Xeljanz XR). If the member has a documented clinical reason to avoid JAK inhibitors (see Appendix B) or is a documented primary nonresponder 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 ustekinumab product, and the member meets both of the following:
  - Member has had a documented intolerable adverse event to all of the primary preferred ustekinumab products (Pyzchiva SC, Stelara SC, and 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).
  - Member has a documented inadequate response or intolerable adverse event with all of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz], Rinvoq, Skyrizi SC, Tremfya SC, Velsipity, and Zeposia) and the secondary preferred product (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 products from the respective class.
- The requested product is Entyvio SC.
- The requested product is Omvoh SC and the member received Omvoh IV for induction therapy.
- The requested product is Xeljanz/Xeljanz XR, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Hyrimoz, Pyzchiva SC, Rinvoq, Skyrizi SC, Stelara SC, Tremfya SC, Velsipity, Yesintek SC, Zeposia).
- The requested product is Omvoh SC, Simponi, 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.

### Non-Radiographic Axial Spondyloarthritis

• Member has had a documented inadequate response or intolerable adverse event with all of the preferred products (Cimzia syringe, Cosentyx SC, and Rinvoq). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) or JAK inhibitors (see

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Appendix B), then the member would not need to use the corresponding preferred products from the respective class.

• Member is currently receiving treatment with a targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.

### Polyarticular Juvenile Idiopathic Arthritis

- Member has a documented inadequate response or intolerable adverse event with both of the primary preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz] and Enbrel) and the secondary preferred product (Cimzia syringe), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
- 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 both of the primary
    preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp),
    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 the primary preferred product (Enbrel) and the secondary preferred product (Cimzia syringe).
- The requested product is Cimzia syringe, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- The requested product is Cimzia syringe, and the member has a documented inadequate response or intolerable adverse event with at least two of the primary preferred products (adalimumab-adaz, adalimumab-fkjp, Enbrel, Hyrimoz).
- The requested product is Actemra SC/Actemra Actpen, Cimzia syringe, Orencia SC/Orencia ClickJect, or Tyenne 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.

### Hidradenitis Suppurativa

- Member has a documented inadequate response or intolerable adverse event with both of the preferred products (an adalimumab product [adalimumab-adaz, adalimumab-fkjp, or Hyrimoz] and Cosentyx SC), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
- 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 both of the preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp) and the adverse event was not an expected adverse event attributed to the active ingredient as

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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 the preferred product (Cosentyx SC).
- 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.

#### Uveitis

Member has had a documented intolerable adverse event to both of the preferred adalimumab products ([adalimumab-adaz or Hyrimoz] and adalimumab-fkjp) 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).

### Alopecia Areata

Member has had a documented inadequate response or intolerable adverse event with the preferred product (Litfulo).

## Exception Criteria for Physician-Administered Products

Coverage for a physician-administered targeted product, see Table 2 above, is provided when any of the following criteria is met:

- For Actemra IV, Cosentyx IV, Orencia IV, Tofidence IV, and Tyenne IV, when the member meets one of the following:
  - Member has a documented inadequate response or intolerable adverse event with both of the preferred products (an infliximab product [Avsola or Remicade] and Simponi Aria) where the products' indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).
  - Orencia IV is being used as a loading dose in a member with a diagnosis of rheumatoid arthritis and the member will be using Orencia SC/Orencia ClickJect for maintenance therapy.
  - Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.
- For Entyvio IV, when the member meets one of the following:
  - Entyvio IV is being used for a diagnosis of ulcerative colitis.
  - Entyvio IV is being used for a diagnosis of Crohn's disease and the member has a documented inadequate response or intolerable adverse event with all of the preferred

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products (an infliximab product [Avsola or Remicade], Skyrizi IV, Tremfya IV, and an ustekinumab product [Pyzchiva IV, Stelara IV, or Yesintek IV]). If the member has a documented clinical reason to avoid TNF inhibitors (see Appendix A) 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.

- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.
- For a targeted infliximab IV product, when the member meets both of the following:
  - Member has had a documented intolerable adverse event to both of the preferred infliximab products (Avsola and Remicade), 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 meets either of the following:
    - The requested product is being used for a diagnosis of Crohn's disease or ulcerative colitis, and the member has a documented inadequate response or intolerable adverse event with all of the preferred products (Skyrizi IV, Tremfya IV, and an ustekinumab product [Pyzchiva IV, Stelara IV, or Yesintek IV), unless the member is a documented primary non-responder to an IL-23 inhibitor.
    - Member has a documented inadequate response or intolerable adverse event with both of the preferred products (Ilumya and Simponi Aria) where the products' indications overlap.
- For Cimzia lyophilized powder, when the member meets one of the following:
  - The requested product is being used for a diagnosis of Crohn's disease, and the member has a documented inadequate response or intolerable adverse event with all of the preferred products (an infliximab product [Avsola or Remicade], Skyrizi IV, Tremfya IV, and an ustekinumab product [Pyzchiva IV, Stelara IV, or Yesintek IV]), unless the member is a documented primary non-responder to an IL-23 inhibitor.
  - Member has a documented inadequate response or intolerable adverse event with all of the preferred products (an infliximab product [Avsola or Remicade], Ilumya, and Simponi Aria) where the products' indications overlap.
  - 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.
- For Omvoh IV, when the member meets one of the following:
  - The requested product is being used for a diagnosis of Crohn's disease or ulcerative colitis, and the member has a documented inadequate response or intolerable adverse event with all of the preferred products (an infliximab product [Avsola or Remicade], Skyrizi IV, Tremfya IV, and an ustekinumab product [Pyzchiva IV, Stelara IV, or Yesintek IV]), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).

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- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.
- For a targeted ustekinumab IV product, when the member meets both of the following:
  - Member has had a documented intolerable adverse event to all of the preferred ustekinumab products (Pyzchiva IV, Stelara IV, and Yesintek IV), 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).
  - The requested product is being used for a diagnosis of Crohn's disease or ulcerative colitis, and the member has a documented inadequate response or intolerable adverse event with all of the preferred products (an infliximab product [Avsola or Remicade], Skyrizi IV, and Tremfya IV), unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix A).

## 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

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