

**ZYMFENTRA
(infliximab-dyyb)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severely active Crohn's disease (CD)
 - a. Inadequate treatment response, intolerance, or contraindication to conventional therapy for CD (See Appendix 1)
2. Moderate to severely active ulcerative colitis (UC)
 - a. Inadequate treatment response, intolerance, or contraindication to conventional therapy for UC (See Appendix 1)

AND ALL of the following:

1. Patient will have completed an intravenous (IV) induction regimen with an infliximab product before starting Zymfentra
2. TB test confirming no active tuberculosis **OR** if latent tuberculosis infection is present, treatment for the infection to be started prior to use of infliximab products
3. **NO** active infections
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 2)
5. Patient is not at risk for HBV infection **OR** is at risk for HBV infection and HBV infection has been ruled out **OR** treatment for HBV infection has been initiated
6. **NOT** given concurrently with live vaccines
7. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval Limits

Quantity 4 injections per 56 days

Duration 4 months



**BlueCross
BlueShield**

Federal Employee Program.

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Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severely active Crohn's disease (CD)
2. Moderate to severely active ulcerative colitis (UC)

AND ALL of the following:

1. Condition has improved or stabilized
2. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 2)
4. **NOT** given concurrently with live vaccines
5. Patient **MUST** have tried the preferred product(s) (see Appendix 3) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval *Renewal* Limits

Quantity 4 injections per 56 days

Duration 12 months

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Appendix 1 - List of Conventional Therapies

Conventional Therapy Options for CD	
1. Mild to moderate disease – induction of remission:	<ul style="list-style-type: none"> a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission:	<ul style="list-style-type: none"> a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:	<ul style="list-style-type: none"> a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:	<ul style="list-style-type: none"> a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission	<ul style="list-style-type: none"> c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission	<ul style="list-style-type: none"> d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC	
1. Mild to moderate disease – induction of remission:	<ul style="list-style-type: none"> a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:	<ul style="list-style-type: none"> a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:	<ul style="list-style-type: none"> a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:	<ul style="list-style-type: none"> a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine
5. Pouchitis:	<ul style="list-style-type: none"> a. Metronidazole, ciprofloxacin b. Alternative: rectal mesalamine

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Appendix 2 – List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytosan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
infliximab	Zymfentra
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz
upadactinib	Rinvoq



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Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Crohn's disease (CD)	*must try TWO preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira
Ulcerative colitis (UC)	*must try TWO preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira

**Including all preferred biosimilars (see reference product criteria)