DEPARTMENT:	Utilization Management
SUBJECT:	Inflammatory Bowel Disease Treatments
PRODUCT LINE:	All
POLICY NUMBER:	HM 99
ORIGINAL POLICY EFFECTIVE DATE:	11/01/2017
LAST REVISED DATE:	01/22/2024
LAST REVIEWED DATE:	03/07/2024

group health Cooperative of eau claire

KMTSJ, Inc.

SCOPE: To ensure Group Health Cooperative of Eau Claire (the Cooperative) consistently and correctly administers benefits to all members according to their policy benefits.

POLICY: It is the policy of the Cooperative to review requests for inflammatory bowel disease (Crohn's and Ulcerative colitis) treatments according to member policy and evidence-based medical criteria through the prior authorization process. All first line and second line treatments below are covered under the pharmacy benefit because they are expected to be self-administered by the member in their home.

PROCEDURE: Prior Authorization Required: YES

Coverage Criteria for Crohn's

First line treatments:
First line treatment for Crohn's disease includes the following conventional therapies:

5-aminosalicylates:
1. Sulfasalazine
2. Mesalamine

Immunosuppressants:
1. 6-mercaptopurine
2. Azathioprine
3. Corticosteroids (prednisone, methylprednisolone)
4. Methotrexate

Second line treatments:
Member must have a diagnosis of moderate to severe Crohn's disease and must have had an insufficient response (at least 12 weeks of treatment) to at least 4 or 5 of the conventional therapies listed under first line treatments and one must be methotrexate or an intolerance/contraindication to ALL of the therapies listed under first line treatments.

TNF:
1. adalimumab (Humira) 4mg SQ every 2 weeks
2. certolizumab (Cimzia) 200mg SQ every 2 weeks
3. golimumab (Simponi) 50mg SQ every 4 weeks

IL Antagonist:
1. ustekinumab (Stelara) SQ every 8 weeks with one IV loading dose

Third line treatments:
Member must have failed first line treatments and at least two of the second line treatments list above before a third line treatment will be approved. When a member meets for a third line treatment, Skyrizi would be approved first. If they have failed Skyrizi, then infliximab would be approved next. α-4 integrin inhibitors would be approved last.

TNFs:
1. infliximab (Renflexis, Inflectra, Remicade) 3mg/kg IV every 8 weeks. When the member meets criteria for infliximab approve Renflexis which is the least costly product. If Renflexis is not available then approve Inflectra. Remicade should be denied as it is the most costly product. Commercial members receiving Remicade as a home infusion through Option Care/Ministry can receive Remicade only if administered through the home health agencies listed here.

α-4 Integrin Inhibitors:
1. Vedolizumab (Entyvio) 300mg IV every 8 weeks
2. Natalizumab (Tysabri) 300mg IV every 4 weeks

IL Antagonist:
1. Risankizumab (Skyrizi) induction dosage of 600mg administered by IV infusion over at least one hour at Week 0, week 4, and week 8. The recommended maintenance dosage is 360mg administered by subQ injection at week 12 and every 8 weeks thereafter

Coverage Criteria for Ulcerative Colitis

First line treatments:

5-aminosalicylates:
1. Sulfasalazine
2. Mesalamine

Immunosuppressants:
1. 6-mercaptopurine
2. Azathioprine
3. Corticosteroids (prednisone, methylprednisolone)

Second line treatments:
Member must have a diagnosis of moderate to severe ulcerative colitis and must have had an insufficient response to at least 4 of the conventional therapies listed under first line treatments or an intolerance/contraindication to ALL of the therapies listed under first line treatments.

Janus Kinase Inhibitors:

1. tofacitinib (Xeljanz) PO

Sphingosine 1-Phosphate (S1P) Receptor Modulator:

1. ozanimod (Zeposia) .92mg PO QD (For commercial product lines other than ETF, would need to fail more conservative, cost effective SQ 2nd line treatments.)

TNF:

1. adalimumab (Humira) 4mg SQ every 2 weeks
2. certolizumab (Cimzia) 200mg SQ every 2 weeks
3. golimumab (Simponi) 50mg SQ every 4 weeks

IL Antagonist:

1. ustekinumab (Stelara) SQ every 8 weeks with one IV loading dose

Third line treatments:

Member must have failed first line treatments and at least two of the TNF second line treatments list above in addition to ustekinumab and tofacitinib before a third line treatment will be approved.

TNF:

1. Infliximab (Renflexis, Inflectra, Remicade) 3mg/kg IV every 8 weeks. When the member meets criteria for infliximab approve Renflexis which is the most cost effective product. If Renflexis is not available then approve Inflectra. Remicade should be denied as it is the least cost effective product unless it is a commercial member who is receiving Remicade as a home infusion through Option Care or Ministry Home Infusion.

α-4 Integrin Inhibitors:

1. Vedolizumab (Entyvio)
    a. 300mg IV every 8 weeks
    b. SubQ 108mg every 2 weeks (after two initial IV loading doses, UC only)

APPROVED: _____ DATE: 03/07/2024

REVISION HISTORY:

Rev. Date	Revised By/Title	Summary of Revision
12/12/2018	Michele Bauer, MD, CMO	Reviewed without changes
04/08/2019	Michele Bauer, MD, CMO	Removed Enbrel from the criteria
05/05/2020	Michele Bauer, MD, CMO	Reviewed without changes.
06/09/2020	Michele Bauer, MD, CMO	Updated to include Stelara, Tysabri, and Xeljanz
09/15/2020	Michele Bauer, MD, CMO	Updated failed treatment length
09/20/2021	Michele Bauer, MD, CMO	Reviewed without changes.
03/14/2022	Michele Bauer, MD, CMO	Added Zeposia
03/06/2023	Dakota Rau, PharmD	Added Skyrizi
01/22/2024	Dakota Rau, PharmD	Added SubQ Entyvio
03/07/2024	Dakota Rau, PharmD	Reviewed. No changes.