MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Acute and Chronic Bowel Disease	**P&T DATE**	6/10/2025
THERAPEUTIC CLASS	Gastrointestinal Disorders	**REVIEW HISTORY** (MONTH/YEAR)	Previous Chronic Bowel Disease: 6/24. 6/23, 9/21, 5/20, 5/19, 2/18, 2/17, 2/16, 2/15, 2/13 Previous Bowel Movements: 5/20, 9/19, 9/18, 12/16, 9/15, 9/12, 5/08, 11/22
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

❖ PART 1: INFLAMMATORY BOWEL DISEASE OVERVIEW

Inflammatory bowel disease (IBD) is the chronic inflammation of a part (Ulcerative Colitis) or of an entire (Crohn's Disease) digestive tract. Although the exact etiology of IBD is unknown, effective management of IBD and its symptoms help in improving a patient's quality of life. Health Plan of San Joaquin/Mountain Valley Health Plan has adopted the treatment goals and recommendations of the most recent practice guidelines from the American College of Gastroenterology (ACG) and National Institute for Health and Care Excellence (NICE) in the management of Ulcerative Colitis and Crohn's Disease.[1,2] The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents and to help members towards induction and maintenance of remission of symptoms.

Available IBD Non-Biologic Agents: (Current as of 01/2025)

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (restrictions)
Oral Amino-salicylates				
--	**Sulfasalazine (Azulfidine)**	Tablets, IR: 500 mg Tablets, DR: 500 mg	Yes	No
--	**Balsalazide (Colazol)**	Capsules: 750 mg	Yes	No
--	**Mesalamine (Apriso)**	Tablets, ER: 0.375 mg	Yes	No
--	**Mesalamine (Delzicol)**	Capsules, DR: 400 mg	Yes	No
--	**Mesalamine (Pentasa)**	Capsules: CR: 250 mg, 500 mg	Yes	No
--	**Mesalamine (Lialda)**	Tablets, DR: 1.2 mg	Yes	No
--	**Mesalamine (Asacol HD)**	Tablets DR: 800 mg	Yes	No
--	**Olsalazine (Dipentum)**	Capsules: 250 mg	Yes	No

Topical Amino-salicylates				
--	**Mesalamine** (Rowasa)	Enema Solution: 4 GM/60 ml	Yes	No
--	**Mesalamine** (Canasa)	Suppository: 1000 mg	Yes	No
Cortico-steroids				
--	**Prednisone** (Deltasone)	Tablets: 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg, Solution: 5mg/5ml	Yes	No
--	**Budesonide (Entocort, Uceris)**	Delayed release: 3 mg capsules Extended release 24-hour tablets: 9 mg Rectal Foam: 2 mg	Yes	No
Immuno-modulators				
--	**6-Mercaptopurine**	Tablets: 50 mg	Yes	No
--	**Azathioprine (Azasan, Imuran)**	Tablets: 50 mg , 75 mg 100 mg	Yes	No
PA = Prior Authorization; QL = Quantity Limit; IR = Immediate Release; DR = Delayed Release; CR = Controlled Release; SR = Sustained				

Anti-inflammatory Biologic Agent*s:*

CPT code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Medical Benefit (Restrictions)
Tumor Necrosis Factor-α Blockers				
J0135	**Adalimumab (Humira)** *SQ injection*	Pen-injector Kit, Prefilled Syringe kit: 20mg/0.4ml, 40mg/0.8ml	Yes	No
--	Adalimumab biosimilars **Adalimumab-adbm** (Cyltezo), **Adalimumab-atto** (Amjevita) **Adalimumab-afzb** (Abrilada) **Adalimumab-bwwd** (Hadlima)		Yes	No
J0717	**Certolizumab** (Cimzia) **(For Crohn's Disease only)**	Vials, auto-injector, prefilled syringes: 200mg/ml	Yes, for prefilled syringes and auto-injectors	Yes, for vials (PA)
J1602 for IV solution	**Golimumab** (Simponi) **(For Ulcerative Colitis only)**	Auto-injector, prefilled syringe: 50mg/0.5ml, 100mg/ml Solution: 50mg/4ml	Yes, for auto-injector and prefilled syringe	No (IV dosing is not indicated for UC)
J1745	**Infliximab** (Remicade)	Solution: 100mg	Yes	Yes (PA)
Q5103	**Infliximab-dyyb** (Inflectra)	Solution: 100mg	Yes	Yes (PA)
Q5104	**Infliximab-abda** (Renflexis)	Solution: 100mg	Yes	Yes (PA)
Q5121	**Infliximab-axxq** (Avsola)	Solution: 100mg	Yes	Yes (PA)
Q5109	**Infliximab-qbtx** (Ixifi)	Solution: 100mg	Yes	Yes (PA)
--	**Infliximab-dyyb** (Zymfentra)	Solution: 120 mg/mL	Yes	No
Janus Associated Kinase Inhibitor				
--	**Tofacitinib** (Xeljanz)	Tablets: 5mg, 11mg Tablets, XR: 11 mg, 22 mg Oral solution: 1mg/mL	Yes	No
--	**Upadacitinib** (Rinvoq)	Tablets: 15 mg, 30 mg, 45 mg	Yes	No
Sphingosine 1-Phosphate (S1P) Receptor Modulator				
--	**Ozanimod** (Zeposia)	Capsule: 0.23 mg, 0.46 mg, 0.92 mg	Yes	No
--	**Etrasimod** (Velsipity)	Tablets: 2 mg	Yes	No

IL-12, IL-23 Inhibitor				
J3358 (for IV infusion)	**Ustekinumab (Stelara)** *IV infusion* *SQ Syringe*	Prefilled syringe: 45 mg/0.5 ml , 90 mg/ml Solution: 45/0.5mL, 130 mg/26mL	Yes	Yes (PA, for IV infusion only)
Q5138 (for IV infusion)	**Ustekinumab-auub (Wezlana)** *IV infusion* *SQ Syringe*	Subcutaneous solution, prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
Q9997 (for IV infusion)	**Ustekinumab-ttwe (Pyzchiva)**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
Q9999	**Ustekinumab-aekn (Selarsdi)**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
Q9998	**Ustekinumab-aauz (Otulfi),**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
--	**Ustekinumab-srlf (Imuldosa)**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
Q5099	**Ustekinumab-stba (Steqeyma)**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
Q5100	**Ustekinumab-kfce (Yesintek)**	Prefilled syringe: 45 mg/0.5 mL, 90 mg/mL IV Solution: 130MG/26ML	Yes	Yes (PA, for IV infusion only)
IL-23 Inhibitor				
J2327 (for IV infusion)	**Risankizumab (Skyrizi)** *IV infusion* *SQ injection*	Solution: 600 mg/10 mL Auto-injector: 150 mg/mL Cartridge: 180 mg/1.2mL, 360 mg2.4mL Prefilled syringe: 150 mg/mL	Yes	Yes (PA, for IV infusion only)
J2267	**Mirikizumab (Omvoh)** *IV infusion* *SQ injection*	Solution: 300 mg/15 mL Solution Auto-injector: 100 mg/mL Solution Prefilled Syringe 100 mg/mL	Yes	Yes (PA, for IV infusion only)
J1628	**Guselkumab (Tremfya)** *IV infusion* *SQ injection*	Solution: 200 mg/20 mL Solution Auto-injector : 100 mg/mL, 200 mg/2 mL Prefilled Syringe: 100 mg/mL, 200 mg/2 mL	Yes	Yes (PA, for IV infusion only)
Selective Adhesion Molecule Inhibitor				
J2323	**Natalizumab (Tysabri)** *IV infusion*	Solution: 300 mg/15mL	Yes	Yes (PA)
Q5134	**Natalizumab-sztn (Tyruko)**	Solution: 300 mg/15 mL	Yes	Yes (PA)
J3380	**Vedolizumab (Entyvio)** *IV infusion*	Solution: 300 mg	Yes	Yes (PA)

PA = Prior Authorization; QL = Quantity Limit; IR = Immediate Release; DR = Delayed Release; CR = Controlled Release; SR = Sustained

❖ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ/MVHP Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ/MVHP will make the determination based on Medical Necessity as described in HPSJ/MVHP Medical Review Guidelines (UM06).

Tumor Necrosis Factor α Blockers
Infliximab-abda (Renflexis),Infliximab-dyyb (Inflectra), Adalimumab (Humira), Adalimumab (Cyltezo), Certolizumab Pegol (Cimzia), Golimumab (Simponi)

Infliximab (Remicade), Infliximab-abda (Renflexis),Infliximab-dyyb (Inflectra), Infliximab-axxq (Avsola), Certolizumab Pegol (Cimzia):

- ❒ **Coverage Criteria:**
  - **Remicade/Inflectra/Renflexis/Avsola:**
    - Reserved for treatment failure to adequate trial of oral immunosuppressive agents (Azathioprine, Mercaptopurine, Mesalamine, and Sulfasalazine) OR intolerance to corticosteroids.
  - **Cimzia:** Reserved for treatment of Crohn's disease and must meet one of the following:
    - [1] Reserved for treatment failure to adequate trial of oral immunosuppressive agents (Azathioprine, Mercaptopurine, Mesalamine, and Sulfasalazine) OR intolerance to corticosteroids OR
    - [2] women that are currently pregnant or breastfeeding.
- ❒ **Limits:** Must be prescribed by a gastroenterologist.

Selective Adhesion Molecule Inhibitor
Natalizumab (Tysabri), Vedolizumab (Entyvio)

Natalizumab (Tysabri):

- ❒ **Coverage Criteria:** *(for the treatment of Crohn's disease)* Reserved for patients with contraindication to ALL other agents.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documentation showing contraindication to ALL other agents and a negative anti-JCV antibody detection test result.
  - Must be initiated by a gastroenterologist.

Vedolizumab (Entyvio):

- ❒ **Coverage Criteria:** Reserved for treatment of Ulcerative Colitis or Crohn's disease with treatment failure or intolerance to one TNF inhibitor for 2 months.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documentation showing fill history or documentation of treatment failure or intolerance to TNF inhibitors.
  Must be initiated by a gastroenterologist.

IL-12, IL-23 Inhibitors
Ustekinumab (Stelara), Risankizumab (Skyrizi), Mirikizumab (Omvoh)

Ustekinumab (Stelara, Otulfi):

For the treatment of Crohn's Disease

- ❒ **Coverage Criteria*:*** Reserved for treatment failure to **tumor necrosis factor (TNF) inhibitors.**
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Fill history or documentation of treatment failure to tumor necrosis factor (TNF) inhibitors.
- ❒ **Notes:** Must be prescribed by gastroenterologist.

For the treatment of Ulcerative Colitis:

- ❒ **Coverage Criteria:** Reserved for treatment failure to **tumor necrosis factor (TNF) inhibitors.**
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documented diagnosis of moderate to severe ulcerative colitis and fill history or documentation of treatment failure to tumor necrosis factor (TNF) inhibitors.
- ❒ **Notes:** Must be prescribed by gastroenterologist.

Risankizumab (Skyrizi):

For the treatment of Crohn's Disease:

- ❒ **Coverage Criteria*:*** Reserved for treatment failure to **tumor necrosis factor (TNF) inhibitors** AND have tried and failed **Stelara**.
- ❒ **Limits:** NONE

- ❒ **Required Information for Approval:** Fill history or documentation of treatment failure to tumor necrosis factor (TNF) inhibitors.
- ❒ **Notes:** Must be prescribed by gastroenterologist.

Mirikizumab (Omvoh):

For the treatment of Ulcerative Colitis and Crohn's disease:

- ❒ **Coverage Criteria:** Reserved for treatment failure to **tumor necrosis factor (TNF) inhibitors** AND have tried and failed **Stelara.**
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Documented diagnosis of moderate to severe ulcerative colitis and fill history or documentation of treatment failure to TNF inhibitor.
- ❒ **Notes:** Must be prescribed by gastroenterologist.

Guselkumab (Tremfya):

For the treatment of Crohn's Disease and Ulcerative colitis

- ❒ **Coverage Criteria***:* Reserved for treatment failure to **tumor necrosis factor (TNF) inhibitors** AND have tried and failed **Stelara**.
- ❒ **Limits:** NONE
- ❒ **Required Information for Approval:** Fill history or documentation of treatment failure to tumor necrosis factor (TNF) inhibitors.
- ❒ **Notes:** Must be prescribed by gastroenterologist.

❖ CLINICAL JUSTIFICATION

American College of Gastroenterology (ACG) and NICE guidelines states 5-ASA effectiveness in irritable bowel disease. Both oral and rectal 5-ASA have are used in mild to moderately active disease states, with combination of oral and rectal therapy resulting in better outcome than with monotherapy. Oral corticosteroids should be used in short term induction therapy due to systemic effects associated with long term use. Although Budesonide is formulated to target ileal area of the colon, given its low bioavailability and efficacy, budesonide is reserved for patients with disease involving ilea area who are intolerant to conventional oral corticosteroid therapy. Immunomodulators and biologics are reserved for moderate to severe disease states due to systemic effects on immune system.

The 2019 ACG Clinical Guideline for Ulcerative Colitis in Adults recommends vedolizumab for induction of remission with moderate to severely active UC in patients who have previously failed anti-TNF therapy. The 2018 ACG Clinical Guideline for Management of Crohn's Disease in Adults indicates that for patients with moderately to severely active CD and objective evidence of active disease, anti-integrin therapy (with vedolizumab) with or without an immunomodulator is more effective than placebo and should be considered to be used for induction of symptomatic remission in patients with Crohn's disease.

The American Gastroenterological Association released a report for Inflammatory Bowel Disease in Pregnancy in 2019 that indicates aminosalicylates, biologics, or immunomodulator therapies may be continued during pregnancy and through delivery.[38] The guidelines indicate while most biologics, aside from certolizumab, actively cross the placenta, safety data from prospective trials and large nationwide cohorts of women who continued taking biologics in pregnancy have not shown an increase in adverse fetal outcomes.[38] Per the package insert, certolizumab pegol concentrations were minimal/undetectable in multiple samples of infant plasma and in breast milk. Providers who place greater importance for known safety profiles for pregnant and breastfeeding patients

may preference biologic therapy. Hence, patients that are pregnant or currently breastfeeding and have a clinical indication for Cimzia treatment can bypass usual step therapy requirements for Cimzia treatment.[28-37]

Guselkumab (Tremfya) is an Interleukin-23 Inhibitor approved for an IV formulation for the indications of Crohn disease and Ulcerative colitis. It carries a similar role and mechanism of action to other IL-23 inhibitors such as Skyrizi and Omvoh.

PART 2: IRRITABLE BOWEL SYNDROME, CONSTIPATION & DIARRHEA OVERVIEW

Inflammatory bowel syndrome (IBS) is a common disorder of bowel function that causes change in bowel habits resulting in either constipation (IBS-C) or diarrhea (IBS-D), along with symptoms such as abdominal pain, bloating, and other non-intestinal symptoms. Although the exact etiology of IBS is unknown, effective management of IBS and its symptoms help in improving a patient's quality of life. Health Plan of San Joaquin/Mountain Valley Health Plan has adopted the treatment goals and recommendations of the most recent practice guidelines from the American Gastroenterological Association (AGA) and The National Institute for Health Care and Excellence Guidelines (NICE) in the management of IBS-C and IBS-D.[1,2,12] The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents.

Constipation affects approximately about -12 million Americans.[25] Many of the people with chronic constipation are on pain medication worsening constipation. Basic effects of opioid induced constipation is mechanically different from other forms of constipation.

Acute diarrhea can be defined as the passage of a greater number of stools of decreased form from the normal lasting less than 14 days, while persistent diarrhea is defined as diarrhea lasting between 14 and 30 days and chronic diarrhea lasts for greater than 30 days. Diarrhea can be caused by a number of factors, including infection. Acute diarrheal infection (also called gastroenteritis) is a leading cause of outpatient visits, hospitalizations, and lost quality of life occurring in both domestic settings and among travelers. According to the American College of Gastroenterology, use of antibiotics for community-acquired diarrhea should be discouraged as most cases are viral in origin & not shortened with antibiotics.[15]

Prescription & OTC constipation and diarrhea medications are used to relieve symptoms and/or regulate bowel movements. While there are many available agents to relieve constipation and diarrhea, non-pharmacologic recommendations should be incorporated into every patient care plan. The purpose of this coverage policy is to review HPSJ/MVHP's coverage criteria of constipation and diarrhea agents.

Available IRRITABLE BOWEL SYNDROME, CONSTIPATION & DIARRHEA Agents (Current as of 1/2025):

CPT code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
		Bulk Forming		
--	Psyllium Husk with Sugar (Metamucil, Natural Fiber, Konsyl)	3.4 gram/7 gram powder, 3.4 gram oral powder packet	Yes	No
--	Psyllium Husk with Aspartame (Metamucil Fiber)	3.4 gram/5.8 gram powder, 3.4 gram oral powder packet	Yes	No
--	Psyllium Seed (Reguloid, Hydrocil Instant)	Reguloid Laxative Powder, Hydrocil Instant Packet	Yes	No
--	Psyllium Seed with Dextrose (Natural Fiber Lax, Fiber Smooth, Konsyl-D, Natural Vegetable Laxative Powder)	Fiber oral powder, Metamucil Fiber Wafer 2.5 gram oral Wafer	Yes	No
		Osmotic		
--	Polyethylene Glycol 3350 (Miralax, Clearlax, Purelak, Gavilax, Smoothlax)	17gram/dose oral powder jar, 17g/dose oral powder packet	Yes	No
--	Peg 3350/Na Sulf/ Bicarb/Cl/KCl (Gavilyte, Golytely, Colyte)	Gavilyte-C 240 gram-22.72 gram-6.72 gram-5.84 gram oral solution, Gavilyte-G 236 gram-22.74 gram-6.74 gram-5.86 gram oral solution, PEG 3350 and ELS, Golytely 236 gram-22.74 gram-6.74 gram-5.86 gram oral	Yes	No

		solution, Golytely 227.1 gram-21.5 gram-6.36 gram oral packet,		
--	Sodium chloride/ NaHCO3/KCl/Peg (Trilyte, Gavilyte-N, Nulytely)	Trilyte With Flavor Packets 420 gram oral solution, PEG 3350 and ELS, Gavilyte-N 420 gram solution, Nulytely With Flavor Packets	Yes	No
--	Sodium/Potassium/Mag Sulfates (Suprep Bowel Prep)	Suprep Bowel Prep Kit 17.5-3.13 gram oral solution	Yes	No
--	Magnesium Hydroxide (Milk of Magnesia)	400mg/5mL suspension	Yes	No
--	Magnesium Citrate (Citroma)	1.745g/30mL solution (296mL Bottle)	Yes	No
--	Glycerin (Fleet Pedia-Lax, Sani-Supp)	Adult rectal suppository, Child rectal suppository, Fleet Glycerin 5.4 gram/5.4 mL liquid rectal suppository, Pedia-Lax 2.8 gram/2.7 mL rectal solution	Yes	No
Stool Softener				
--	Sennosides/Docusate Sodium (Senna S, Senna Plus)	8.6mg/50mg tablet	Yes	No
Cathartic				
--	Sodium Phosphates (Fleet Enema Extra, OsmoPrep Tablet)	7.2 gram-2.7 gram/15 mL oral liquid, 19 gram-7 gram/197 mL enema, OsmoPrep tablet	Yes	No
Antidiarrheals				
--	Bismuth subsalicylate (Pepto-Bismol, Bismatrol, Kao-Tin)	262 mg chewable tablet, 262 mg tablet, 262 mg/15 ml oral suspension, 525 mg/15 ml oral suspension	Yes	No
--	Diphenoxylate HCl/Atropine (Lomotil)	2.5 mg-0.025 mg liquid, 2.5 mg-0.025 mg tablet	Yes	No
--	Loperamide (Imodium)	2 mg capsule, 2 mg tablet, 1 mg/5 ml oral solution, 1 mg/7.5 ml oral solution	Yes	No
--	Opium Tincture	10 mg/ml tincture	Yes	No
Antispasmodics				
--	Dicyclomine (Bentyl)	10 mg capsule, 10 mg /5 mL solution, 20 mg tablet	Yes	No
--	Hyoscyamine (Anaspaz, Cystospaz, Levsin)	0.125 mg ODT, 0.125 mg tablet SL, 0.375 mg ER tablet, 0.125 mg tablet, 125 mcg/5 mL elixir, 0.125 mg/mL drop	Yes	No
Tricyclic Antidepressants				
--	Amitriptyline (Elavil)	10 mg tablet, 25 mg tablet, 50 mg tablet, 75 mg tablet, 100 mg tablet, 150 mg tablet	Yes	No
--	Clomipramine (Anafranil)	25 mg capsule, 50 mg capsule, 75 mg capsule	Yes	No
--	Desipramine (Norpramin)	10 mg tablet, 25 mg tablet, 50 mg tablet, 75 mg tablet, 100 mg tablet, 150 mg tablet	Yes	No
	Doxepin (Sinquan)	Silenor 3 mg tablet, Silenor 6 mg tablet, 10 mg/5 ml solution, 10 mg capsule, 25 mg capsule, 50 mg capsule, 75 mg capsule, 100 mg capsule, 150 mg capsule	Yes	No
--	Imipramine (Tofranil)	10 mg tablet, 25 mg tablet, 50 mg tablet	Yes	No
--	Nortriptyline (Pamelor)	10 mg/5 ml oral concentrate, 10 mg capsule, 25 mg capsule, 50 mg capsule, 75 mg capsule	Yes	No
--	Trimipramine	25 mg capsule, 50 mg capsule, 100 mg capsule	Yes	No
Chloride Channel Activator				

--	Lubiprostone (Amitiza)	8 mcg capsule, 24 mcg capsule	Yes	No
Guanylate Cyclase-C Agonist				
--	Linaclotide (Linzess)	72 mcg capsule, 145mcg capsule, 290 mcg capsule	Yes	No
--	Plecanatide (Trulance)	3 mg tablets	Yes	No
5-HT3 Antagonist				
--	Alosetron (Lotronex)	0.5 mg tablet, 1 mg tablet	Yes	No
5-HT4 Receptor Agonist				
--	Prucalopride (Motegrity)	1 mg tablet, 2 mg tablet,	Yes	No
--	Tegaserod (Zelnorm)	2 mg tablet, 6 mg tablet	Yes	No
Mixed Mu-Opioid Receptor Agonist, Delta Opioid Receptor Antagonist, And Kappa Opioid Receptor Agonist				
--	Eluxadoline (Viberzi)	75 mg tablets, 100 mg tablets	Yes	No
Peripherally acting Opioid Antagonist				
--	Methylnaltrexone (Relistor)	8 mg/0.4 mL subcutaneous solution, 12 mg/0.6 mL subcutaneous solution, 150 mg tablet	Yes	No
--	Naldemedine (Symproic)	0.2 mg tablet	Yes	No
--	Naloxegol (Movantik)	12.5 mg tablet, 25 mg tablet	Yes	No
Prokinetic				
--	Metoclopramide (Reglan)	5 mg/5 mL solution, 5 mg tablet, 10 mg tablet	Yes	No
Antibiotics				
--	Rifaximin (Xifaxan)	550 mg tablet	Yes	No
Sodium/Hydrogen Exchanger 3 (NHE3) Inhibitor				
--	Tenapanor ***(***Ibsrela)	50 mg tablet	Yes	No

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❖ CLINICAL JUSTIFICATION

HPSJ/MVHP policy is based on current and updated clinical and practice guidelines. According to ACG 2018 IBS treatment monograph recommends exercise, diet and dietary manipulation to improve overall symptoms of IBS. Updated systemic review and meta-analysis on fiber showed statistically significant improvement in fiber compare to placebo. Polyethylene glycol, Tricyclic antidepressants and loperamide improve diarrhea symptoms as well. SSRIs are now recommended to improve constipation in IBS-D. Tegaserod (Zelnorm) has been reintroduced for emergency treatment of IBS-C and chronic idiopathic constipation (CIC) in women (<55 years of age) in which no alternative therapy exists. Tegaserod (Zelnorm) is only available through emergency- investigational new drug (IND) process.

Bowel regimens can be divided into two categories of drugs: agents with active mechanism, such as bisacodyl, magnesium oxide, and lubiprostone; and those with passive mechanisms, such as psyllium husk and docusate. The HPSJ/MVHP formulary is structured to favor fiber and laxatives due to recommendations from the American Gastroenterological Association (AGA).[14] Medications from multiple categories can be combined for patients with inadequate relief from one agent. The whole therapeutic picture should be addressed when treating constipation; calcium channel blockers, opiates, and inadequate management of diabetes (due to dehydration) can exacerbate the condition. Patients should maintain adequate hydration, eat fibrous foods, and exercise regularly to ensure the highest level of effectiveness.

Diarrhea can be treated with symptomatic therapy, such as loperamide, diphenoxylate, or bismuth subsalicylate. If the diarrhea has an infectious cause, antibiotics such as azithromycin, fluoroquinolones, and rifaximin can be used depending on presentation of symptoms or location of where the patient traveled. According to the American College of Gastroenterology (ACG)[15] and Infectious Diseases Society of America (IDSA),[16] the most useful antimotility agent is loperamide. Due to extrapyramidal effects, agents such as Metoclopramide should be limited.

The 2021 ACG Clinical Guideline for the Management of Irritable Bowel Syndrome[27] indicate that loperamide is not recommended as first-line therapy for treating IBS-D symptoms because it may improve diarrhea but not improve global IBS symptoms. The guidelines further indicate that eluxadoline (Viberzi) improves global IBS-D symptoms in men and women, and analyses have also shown that eluxadoline improves symptoms in patients with IBS-D who have failed previous trials of loperamide. Finally, the 2021 guidelines recommend against the use of antispasmodics currently available in the United States to treat global IBS symptoms due to limited data supporting their use, with existing data being decades-old, of poor quality, or methodologically limited.

❖ REFERENCES PART 1

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❖ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Amitiza and Laxatives 5-08.doc	5/2008	Allen Shek, PharmD BCPS
Updated Policy	Formulary Realignment 9-18-12.xlsx	9/2012	Allen Shek, PharmD BCPS
Creation of Policy	Biologics Class Review for Crohns 2013-2-19.docx	2/2013	Allen Shek, PharmD
Update to Policy	IBD Class Review 2-17-15.docx	2/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy - Gastrointestinal - Constipation 2015-05.docx	9/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	Class Review- Biologics, Apremilast, and Tofacitinib in Inflammatory Joint, Skin, and Bowel Diseases.docx	2/2016	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Gastrointestinal - Constipation 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Gastrointestinal – Chronic Bowel Disease 2017-02.docx	2/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Gastrointestinal – Chronic Bowel Disease 2018-02.docx	2/2018	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Gastrointestinal - Constipation 2018-09b.docx	09/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Gastrointestinal – Chronic Bowel Disease 2019-05.docx	5/2019	Matthew Garrett, PharmD
Combined Policy	HPSJ Coverage Policy – Gastrointestinal – Acute and Chronic Bowel Disease 2020-05.docx	5/2020	Matthew Garrett, PharmD
Update to Policy	Acute and Chronic Bowel Disease	9/2021	Matthew Garrett, PharmD
Update to Policy	Acute and Chronic Bowel Disease	11/2022	Matthew Garrett, PharmD
Update to Policy	Acute and Chronic Bowel Disease	09/2023	Matthew Garrett, PharmD
Update to Policy	Acute and Chronic Bowel Disease	06/2024	Matthew Garrett, PharmD
Update to Policy	Acute and Chronic Bowel Disease	06/2025	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy