

Commissioner for the Department for Medicaid Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner of the Department for Medicaid Services (DMS) based on the Drug Review and Options for Consideration document prepared for the Pharmacy and Therapeutics (P&T) Advisory Committee's review on **March 18, 2021** and the resulting official recommendations.

Clinical Criteria Review

Gimoti™: Non-prefer in the PDL class: *Anti-Emetics: Other*

Length of Authorization: 8 weeks

- Gimoti™ (metoclopramide) is a nasally administered dopamine-2 (D2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Criteria for Approval:

- Diagnosis of diabetic gastroparesis; **AND**
- Prescribed by an endocrinologist, gastroenterologist or other specialist in the diagnosis and treatment of diabetic gastroparesis; **AND**
- Prescriber attests that patient does NOT meet ANY of the following conditions:
 - o History of signs or symptoms of tardive dyskinesia (TD);
 - o History of a dystonic reaction to metoclopramide;
 - o Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation);
 - o Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma;
 - o Diagnosis of epilepsy or any other seizure disorder;
 - o Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm);
 - o Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute);
 - o Moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
- Prescriber attests that each course of treatment, with all dosage forms and routes of administration of metoclopramide, will NOT extend beyond 12 weeks; **AND**
- Adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., intramuscular) metoclopramide; **OR**

- NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications).

Renewal Criteria (duration 8 weeks):

- Must continue to meet initial authorization criteria; **AND**
- At least 2 weeks have passed (i.e., drug holiday) since completion of a previous course of metoclopramide treatment of any dosage form; **AND**
- Demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); **AND**
- Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention).

Age Limit: ≥ 18 years

Quantity Limit: 1 bottle (9.8 mL) per 28 days

Drug Class	Preferred Agents	Non-Preferred Agents
Anti-Emetics: Other	meclizine metoclopramide oral solution, tablets prochlorperazine tablets promethazine syrup, tablets promethazine 12.5, 25 mg suppositories scopolamine patches	Compazine® Compro® Bonjesta® CC, QL Diclegis™ CC, QL doxylamine/pyridoxine CC, QL Gimoti™ CC, QL metoclopramide ODT Phenadoz® Phenergan® prochlorperazine suppositories promethazine 50 mg suppositories Reglan® Tigan® Transderm-Scop® trimethobenzamide

Full Class Reviews

Antibiotics, GI

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Antibiotics, GI class*, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Gastrointestinal (GI)	Firvanq™ CC metronidazole tablets neomycin tinidazole vancomycin capsules CC Xifaxan® CC, QL	Alinia® Dificid® QL Flagyl® metronidazole capsules nitazoxanide paromomycin Solosec™ CC, QL Tindamax® Vancocin® vancomycin solution

Hepatitis C Agents

Class Selection & Guidelines

Hepatitis C: Direct-Acting Antiviral Agents

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 first-line treatment regimen should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Hepatitis C: Direct-Acting Antiviral Agents* class, require PA until reviewed by the P&T Advisory Committee.

Hepatitis C: Interferons

- DMS to select preferred agent(s) based on economic evaluation.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Hepatitis C: Interferons* class, require PA until reviewed by the P&T Advisory Committee.

Hepatitis C: Ribavirins

- DMS to select preferred agent(s) based on economic evaluation; however, at least generic ribavirin tablets should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Hepatitis C: Ribavirins* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Hepatitis C: Direct-Acting Antiviral Agents	Mavyret™ CC, QL sofosbuvir/velpatasvir CC, QL Vosevi™ CC, QL	Epclusa® CC, QL Harvoni® CC, QL ledipasvir/sofosbuvir CC, QL Sovaldi™ CC, QL Viekira Pak® CC, QL Zepatier™ CC, QL
Hepatitis C: Interferons	PEGASYS® ProClick CC, QL PEGASYS® syringe CC, QL	PEGASYS® vial CC, QL PEGIntron™ CC, QL
Hepatitis C: Ribavirins	ribavirin CC	Moderiba™ CC ribavirin dosepack CC

Antiretrovirals: HIV/AIDS

Class Selection & Guidelines

- DMS to select preferred agent(s) based on economic evaluation; however, at least 3 first-line treatment regimens should be preferred.
- Agents not selected as preferred will be considered non-preferred and will require PA.
- For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee.

Note: Allow grandfathering of members using agents moving to non-preferred. That is, members may remain on their current product/regimen without (re)trial of a preferred agent.

Drug Class	Preferred Agents	Non-Preferred Agents
Antiretrovirals: HIV/AIDS	abacavir QL abacavir-lamivudine atazanvir QL Atripla® QL	abacavir-lamivudine-zidovudine Aptivus® Combivir® Crixivan®

Drug Class	Preferred Agents	Non-Preferred Agents
	Biktarvy [®] QL Cymduo [™] QL Complera [®] QL Delstrigo [™] QL Descovy [®] CC, QL Edurant [®] efavirenz Emtriva [®] Evotaz [™] QL Genvoya [®] QL Intelence [®] Isentress [®] Kaletra [®] tablet lamivudine QL lamivudine-zidovudine lopinavir-ritonavir solution Odefsey [®] QL Pifeltro [™] QL Prezista [®] ritonavir tablets Selzentry [®] stavudine capsules QL stavudine solution Stribild [®] QL Symfi [™] QL Symfi Lo [™] QL tenofovir disoproxil fumarate tablets QL Tivicay [®] tablets QL Triumeq [®] QL Trizivir [®] Truvada [®] CC, QL Tybost [®] Videx [®] EC QL zidovudine syrup, tablets	didanosine DR QL Dovato [®] QL efavirenz/emtricitabine/tenofovir disoproxil fumarate emtricitabine emtricitabine/tenofovir disoproxil fumarate Epivir [®] QL Epzicom [®] fosamprenavir Fuzeon [®] Invirase [®] Juluca [®] QL Kaletra [®] solution Lexiva [®] nevirapine QL nevirapine ER QL Norvir [®] powder packets Norvir [®] tablets, solution QL Prezcobix [®] QL Retrovir [®] Reyataz [®] Rukobia [®] CC, QL Sustiva [®] Symtuza [™] QL Temixys [™] QL Tivicay [®] suspension QL Videx [®] solution Viracept [®] Viramune [®] QL Viramune XR [®] QL Viread [®] powder packets Viread [®] tablets QL Zerit [®] capsules QL Ziagen [®] QL zidovudine capsules

Intranasal Rhinitis Agents

Class Selection & Guidelines

Intranasal Antihistamines and Anticholinergics

- DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Intranasal Antihistamines and Anticholinergics* class, require PA until reviewed by the P&T Advisory Committee.

Intranasal Corticosteroids

- DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.
- Agents not selected as preferred will be considered non-preferred and require PA.
- For any new chemical entity in the *Intranasal Corticosteroids* class, require PA until reviewed by the P&T Advisory Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Intranasal Antihistamines and Anticholinergics	azelastine 0.1% azelastine 0.15% ipratropium nasal spray	Astepro® olopatadine Patanase™
Intranasal Corticosteroids	fluticasone propionate QL	azelastine/fluticasone QL Beconase AQ® QL budesonide QL Children's Qnasl™ QL Dymista® QL flunisolide QL Nasonex® QL Omnaris™ QL Qnasl™ QL triamcinolone QL Veramyst® QL Xhance™ CC Zetonna™ QL

Classes Reviewed by Consent Agenda

No change in PDL status:

- Absorbable Sulfonamides
- Antibiotics, Inhaled
- Antibiotics, Vaginal
- Antifungals, Oral
- Antihistamines, Minimally Sedating
- Antivirals, Oral
- Bronchodilators, Beta Agonist
- Cephalosporins and Related Antibiotics
- COPD Agents
- Epinephrine, Self-Injected
- Fluoroquinolones, Oral
- Glucocorticoids, Inhaled
- Hepatitis B Agents
- Leukotriene Modifiers
- Macrolides
- Oxazolidinones
- Penicillins
- Pleuromutulins
- Tetracyclines