Optum Rx®

Pharmacy Passages

Formulary Update

April 2024

The following formulary decisions and updates apply to **Optum Rx® commercial business.**

The Optum Rx Business Committee meets monthly to evaluate tier placements and new prescription products approved by the Food and Drug Administration (FDA). This committee makes decisions based on information and recommendations from the Optum Rx National Pharmacy & Therapeutics Committee, comprised of independent physician providers and pharmacists.

The following are the strategic clinical decisions made in the past month. Your actual plan's copays and/or coinsurance may differ from those indicated depending on the selected plan design, which determines coverage and pharmacy provider(s). Refer to your benefit plan documents to make sure the listed medications are included in your benefit.

Please note:
If your plan includes Specialty Pharmacy (SP), your members may obtain specialty products from Optum Specialty Pharmacy for your plan's designated copay or coinsurance. If your plan does not include SP, your members may purchase self-injectable and oral specialty medications from retail pharmacies, or specialty products may be covered under your medical plan. Specialty program medications may be limited to a 30-day supply depending on plan design. Please consult your plan coverage documents.

Available formularies

Select	Three tier formulary with generic drugs included in Tier 1, preferred brand name drugs included in Tier 2 and non-preferred drugs included in Tier 3. Many Tier 3 drugs have lower-cost options in Tier 1 or 2.
Premium	Three tier formulary with generic drugs included in Tier 1. Some drugs may be excluded from the Premium Formulary due to a strategic evaluation of the market, utilization, quality outcomes and total cost of care.
Premium Value (PVF)	Four-tiered, closed formulary with tiering based on net cost, regardless if the drug is a brand or generic. Drugs are added to PVF after a strategic evaluation of the market, utilization, quality outcomes and total cost of care.

Key **SP:** Specialty Pharmacy **PA:** Prior Authorization **ST:** Step Therapy **QL:** Quantity Limits

FDA approves the first gene therapy for rare disease of metachromatic leukodystrophy in children

On March 18, 2024, the FDA approved Lenmeldy (atidarsagene autotemcel) to treat metachromatic leukodystrophy. Lenmeldy is indicated for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile or early symptomatic early juvenile metachromatic leukodystrophy. Lenmeldy is available as a single-dose cell suspension for intravenous infusion.

Metachromatic leukodystrophy (MLD) is a rare, autosomal recessive, inherited lysosomal storage disease. The lack of an enzyme called arylsulfatase A (ARSA) leads to the accumulation of fatty substances called sulfatides in the cells of the brain, spinal cord, nerves, liver, and kidneys. The accumulation of sulfatides begins to destroy the protective layer of the nerves called the myelin sheath. This damages the nerves and causes progressive motor issues, such as weakness, cognitive decline, and death. There is no cure for this condition, and no treatment can reverse damage that has occurred. Treatment typically consists of supportive care and varies depending on the symptoms and how quickly the disease is progressing. Options may include physical therapy and occupational therapy, as well as mental health therapy and support.

Lenmeldy is a **one-time** gene therapy developed by using the child's own blood stem cells and adding functional copies of the ARSA gene to their cells. The newly modified stem cells supply the body with immune cells that produce the ARSA enzyme, which helps break down the build-up of sulfatides. This may allow the child to produce sufficient ARSA enzyme to stop or slow the progression of MLD symptoms.

The Optum Rx National Pharmacy & Therapeutics Committee is thoroughly assessing Lenmeldy for clinical value and safety. Afterwards, Optum Rx will determine its place on the Optum Rx standard formularies.

Down-tiers

Medications may move to a lower tier throughout the year, helping members take immediate advantage of cost savings. Utilization management strategies such as Step Therapy, Quantity Limits or Prior Authorization may apply.

Therapeutic use	Medication name	Brand/ Generic	Select Tier	Premium Tier	Effective date
Anti-Obesity Agents	Saxenda (liraglutide) SC injection	Brand	**3 > 2**	**3 > 2**	4/22/24
	Wegovy (semaglutide) SC injection	Brand	**3 > 2**	**3 > 2**	4/22/24
	Zepbound (tirzepatide) SC injection	Brand	**3 > 2**	**EXC > 2**	4/22/24

EXC: Excluded

Up-tiers

Medications typically move to a higher tier on Jan. 1 and July 1 to help reduce member disruption. Brand medications may move to a higher tier at any time when a generic equivalent becomes available. Utilization management strategies such as Step Therapy, Quantity Limits or Prior Authorization may apply.

Please note there are no up-tiers at this time.

Premium Value Up-tiers/Down-tiers

Medications may move to a lower tier or added to the formulary throughout the year, helping members take immediate advantage of cost savings. Medications typically move to a higher tier on Jan. 1 and July 1 to help reduce member disruption. Utilization management strategies such as Step Therapy, Quantity Limits or Prior Authorization may apply.

Therapeutic use	Medication name	Brand/ Generic	PVF Tier	Effective date
Antineoplastic Agents	Ogsiveo (nirogacestat) tablet	Brand	**EXC > 4**	3/1/24
Anti-Obesity Agents	Zepbound (tirzepatide) SC injection	Brand	**EXC > 3**	4/22/24

EXC: Excluded

New Brand Launches

New brand name medications launch throughout the year. Final coverage status is determined after medications are thoroughly reviewed by the Optum Rx National Pharmacy & Therapeutics Committee. New brand launches may include Authorized Brand Alternatives (ABA).

Therapeutic use	Medication name	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
					SP	PA	ST	QL	
Antimalarial Agents	Sovuna (hydroxychloroquine) tablet*	Tier 3	EXC	EXC	---	---	X	---	3/6/24
Antineoplastic Agents	Pemrydi RTU (pemetrexed) IV infusion*	Tier 3	EXC	EXC	X	---	X	---	3/5/24
Endocrine and Metabolic Agents	Rezdiffra (resmetirom) tablet*	Tier 3	EXC	EXC	X	X	---	X	3/18/24
Hematological Agents	Hemlibra (emicizumab-kxwh) SC injection 12 mg/0.4mL	Tier 3	Tier 3	Tier 4	X	---	---	---	3/26/24
Immunological Agents	Simlandi (adalimumab-ryvk) auto-injector SC pen*	Tier 3	EXC	EXC	X	X	---	X	3/28/24
Neurological Agents	Lenmeldy (atidarsagene autotemcel) IV infusion*	Tier 3	EXC	EXC	X	---	---	---	3/22/24

Medications or products added to the New Drugs to Market exclusion list can remain excluded for up to six months. Updates for these products will be listed in the **New Benefit Coverage for Medications Removed from the New Drugs to Market Exclusion List section below.*

Authorized Brand Alternatives (ABA), also referred to as Authorized Generics, are approved brand name medications marketed by either the brand company or another company. Although it does not have the brand name on its label, it is the exact same drug product as the brand product.

EXC: Excluded

New Generic Launches

New generic medication launches occur throughout the year. Generic medications will be placed in Tier 1 on the Select and Premium Formularies. Brand medications may move to a higher tier at any time when a generic equivalent becomes available.

Therapeutic use	Generic medication name	Brand medication name	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
						SP	PA	ST	QL	
ADHD Agents	dextroamphetamine tablet 2.5 mg & 7.5 mg	Zenzedi	Tier 1	Tier 1	EXC	---	---	---	X	3/18/24
Cardiovascular Agents	quinapril-hydrochlorothiazide tablet 10-12.5 mg	Accuretic	Tier 1	Tier 1	Tier 1	---	---	---	---	3/11/24
Corticosteroid Agents	deflazacort tablet	Emflaza	Tier 1	Tier 1	EXC	X	X	---	---	2/9/24
Genitourinary Agents	tiopronin tablet DR	Thiola EC	Tier 1	Tier 1	Tier 4	X	---	---	---	2/28/24

New Benefit Coverage for Medications Removed from the New Drugs to Market Exclusion List

New Drugs to Market updates apply to all plans that have this exclusion list in place. New drugs can be maintained on this list for up to six months. Medications that are removed from this exclusion list have new benefit coverage as shown below.

Therapeutic use	Medication name	Brand/ Generic	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
						SP	PA	ST	QL	
Antidepressant Agents	Zurzuvae (zuranolone) capsule	Brand	Tier 3	Tier 3	EXC	---	X	---	X	5/8/24
Antineoplastic Agents	Fruzaqla (fruquintinib) capsule	Brand	Tier 3	Tier 3	EXC	X	X	---	---	5/11/24

Therapeutic use	Medication name	Brand/ Generic	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
						SP	PA	ST	QL	
Dermatological Agents	Ycanth (cantharidin) topical solution	Brand	Tier 3	Tier 3	EXC	---	X	---	---	4/25/24
Immunological Agents	Omvoh (mirikizumab-mrkz) SC injection & IV infusion	Brand	Tier 3	Tier 3	EXC	X	X	---	X	5/2/24

Specialty Updates

Specialty medication updates include existing medications being added to or removed from the Specialty Pharmacy Program.

Please note there are no specialty medication updates at this time.

PA Prior Authorization

Prior Authorization requires physicians to provide additional clinical information to verify member benefit coverage. This table only shows Prior Authorizations that have been added or removed. Existing utilization management such as Step Therapy and Quantity Limits may still apply.

Therapeutic use	Medication name	Add/Remove	Effective date
Anti-infective Agents	tetracycline tablet	Add	4/1/24
Corticosteroid Agents	Agamree (vamorolone) oral suspension	Add	4/1/24
	Decadron (dexamethasone) tablet	Remove	4/1/24
Genitourinary Agents	Rivfloza (nedosiran) SC injection	Add	4/1/24
Neurological Agents	Wainua (eplontersen) SC injection	Add	4/1/24
Neuromuscular Agents	Zilbrysq (zilucoplan) SC injection	Add	4/1/24
Skeletal Muscle Relaxant/Neurological Agents	cyclobenzaprine-gabapentin capsule	Remove	4/1/24

ST Step Therapy

Step Therapy directs members to try a lower-cost alternative (Step 1) before a higher-cost medication (Step 2) may be eligible for coverage. This table only shows Step Therapy that have been added or removed. Existing utilization management such as Prior Authorizations and Quantity Limits may still apply.

Please note there are no additions or removals of this restriction at this time.

QL Quantity limits

Quantity limits establish the maximum quantity of a drug that is covered within a specified timeframe. This table only shows Quantity Limits that have been added or removed. Existing utilization management such as Prior Authorizations and Step Therapy may still apply.

Therapeutic use	Medication name	Add/Remove	Effective date
Genitourinary Agents	Rivfloza (nedosiran) SC injection	Add	4/1/24
Neurological Agents	Wainua (eplontersen) SC injection	Add	4/1/24

If you would like additional information that is not listed, please contact your Optum Rx representative.

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