



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 first gene therapies to treat patients with sickle cell disease

On Dec. 8, 2023, the FDA approved Casgevy (exagamglogene autotemcel) and Lyfgenia (lovotibeglogene autotemcel) to treat sickle cell disease (SCD). These two treatments mark the first cell-based gene therapies for SCD. Casgevy and Lyfgenia are indicated for the treatment of SCD in patients 12 years and older with recurrent vaso-occlusive crises (VOCs). Both medications are cell suspensions derived from the patients' modified blood stem cells and are administered by blood stem cell transplant as a one-time, single-dose infusion.

Sickle cell disease is a group of inherited red blood cell disorders that results in abnormal hemoglobin formation. Hemoglobin is a protein that carries oxygen to the body's tissues; however, in someone who has SCD, the abnormal hemoglobin causes the red blood cells to become hard and sticky and look like a C-shaped "sickle." As the sickle cells travel through small blood vessels, these cells get stuck and restrict blood flow, limiting the delivery of oxygen throughout the body and causing severe pain. These events are known as VOCs. VOCs can lead to serious complications such as infection, acute chest syndrome and stroke, and the recurrence of these crises can lead to life-threatening disabilities and/or early death. Additionally, the abnormal cells die early, which causes a constant shortage of red blood cells causing anemia. SCD affects approximately 100,000 people in the U.S, most commonly African Americans and, while less prevalent, also Hispanic Americans.

Casgevy is the first FDA-approved therapy utilizing CRISPR/Cas9, a type of genome editing technology. This genome-edited cellular therapy consists of the patient's own blood stem cells where the DNA has been edited by CRISPR/Cas9 technology. The modified cells are administered via a hematopoietic stem cell transplant procedure, resulting in the increased production of fetal hemoglobin (HbF) that facilitates oxygen delivery and prevents the sickling of red blood cells.

Lyfgenia uses a lentiviral vector (gene delivery vehicle) for genetic modification. With Lyfgenia, the patient's blood stem cells are genetically modified to produce HbAT87Q, a gene-therapy derived hemoglobin that functions similarly to hemoglobin A, which is the normal adult hemoglobin produced in persons not affected by sickle cell disease. Red blood cells containing HbAT87Q have a lower risk of sickling and occluding blood flow. These modified stem cells are then delivered to the patient.

The Optum Rx National Pharmacy & Therapeutics Committee is thoroughly assessing Casgevy and Lyfgenia for clinical value and safety. Afterwards, Optum Rx will determine their 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
Ophthalmic Agents	Miebo (perfluorohexyloctane) ophthalmic solution	Brand	3 > 2	EXC > 2	12/21/23

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
Anaphylactic Agents	Auvi-Q (epinephrine) IM/SC auto-injector 0.1mg	Brand	EXC > 3	12/01/23
Angioedema Agents	Veopoz (pozelimab-bbfg) IV/SC injection	Brand	EXC > 3	12/01/23
Anthelmintic Agents	Humatin (paromomycin) capsule	Brand	EXC > 3	12/01/23
Diabetic Supplies	Omnipod GO Kit (insulin infusion disposable pump)	Brand	EXC > 3	12/01/23
	V-GO (insulin infusion disposable pump)	Brand	EXC > 3	12/01/23
Gastrointestinal Agents	Rebyota Fecal (fecal microbiota, live-jslm) suspension	Brand	EXC > 3	12/01/23

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 (ABAs).

Therapeutic use	Medication name	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
					SP	PA	ST	QL	
Antidepressant Agents	Zurzuvae (zuranolone) capsule*	Tier 3	EXC	EXC	---	---	---	---	11/07/23
Antidiabetic Agents	bexagliflozin tablet* (ABA for Brenzavvy)	Tier 3	EXC	EXC	---	---	X	---	10/16/23

Therapeutic use	Medication name	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
					SP	PA	ST	QL	
Antineoplastic Agents	Augtyro (repotrectinib) capsule*	Tier 3	EXC	EXC	X	---	---	---	11/27/23
	Fruzaqla (fruquintinib) capsule*	Tier 3	EXC	EXC	X	---	---	---	11/10/23
	Jylamvo (methotrexate) oral solution*	Tier 3	EXC	EXC	---	---	---	---	11/23/23
	Loqtorzi (toripalimab-tpzi) IV injection*	Tier 3	EXC	EXC	X	---	---	---	11/28/23
	Ogsiveo (nirogacestat) tablet*	Tier 3	EXC	EXC	X	---	---	---	11/29/23
	Rozlytrek (entrectinib) oral pellets	Tier 3	Tier 3	EXC	X	X	---	---	11/30/23
	Truqap (capivasertib) tablet*	Tier 3	EXC	EXC	X	---	---	---	11/20/23
	Xalkori (crizotinib) oral pellets*	Tier 3	EXC	EXC	X	X	---	---	11/22/23
Anti-Obesity Agents	Zepbound (tirzepatide) SC injection*	Tier 3	EXC	EXC	---	X	---	X	11/10/23
Cardiovascular Agents	Inpefa (sotagliflozin) tablet*	Tier 3	EXC	EXC	---	---	X	---	11/09/23
Dermatological Agents	Cabtreo (adapalene-benzoyl peroxide) topical gel*	Tier 3	EXC	EXC	---	---	---	---	11/21/23
Endocrine and Metabolic Agents	Xphozah (tenapanor) tablet*	Tier 3	EXC	EXC	X	---	---	---	11/06/23
Gastrointestinal Agents	Voquezna (vonoprazan) tablet*	Tier 3	EXC	EXC	---	---	---	---	11/07/23
Musculoskeletal Agents	Amjevita (adalimumab-atto) SC injection 20/0.2mL, 40/0.4mL, 80/0.8mL*	Tier 3	EXC	EXC	X	X	---	X	11/23/23

*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	
Anti-gout Agents	colchicine capsule 0.6mg	Mitigare	Tier 1	Tier 1	EXC	---	---	---	---	10/30/23
Hormonal Agents	teriparatide SC injection	Forteo	Tier 1	Tier 1	EXC	X	X	---	---	11/21/23

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	
Anti-infective Agents	Rezzayo (rezafungin) IV injection	Brand	Tier 3	Tier 3	EXC	X	X	---	---	12/29/23
Antineoplastic Agents	Adstiladrin (nadofaragene firadenov-vncg) intravesical suspension	Brand	Tier 3	Tier 3	EXC	X	X	---	---	01/20/24
	Vanflyta (quizartinib) tablet	Brand	Tier 3	Tier 3	EXC	X	X	---	---	01/27/24
Dermatological Agents	Litfulo (ritlecitinib) capsule	Brand	Tier 3	Tier 3	EXC	X	X	---	X	12/01/23
Gastrointestinal Agents	Suflave (PEG 3350-KCl-NaCl-Na-Su-Mg) oral solution	Brand	Tier 3	Tier 3	EXC	---	---	---	---	12/31/23
Genitourinary Agents	Xaciato (clindamycin) vaginal gel	Brand	Tier 3	Tier 3	EXC	---	---	---	---	01/06/24

Therapeutic use	Medication name	Brand/ Generic	Select Tier	Premium Tier	PVF Tier	Programs				Effective date
						SP	PA	ST	QL	
Hematological Agents	Roctavian (valoctocogene roxaparvovec-rvox) IV infusion	Brand	Tier 3	Tier 3	EXC	X	X	---	---	01/19/23
Immunological Agents	Rystiggo (rozanolixizumab-noli) SC injection	Brand	Tier 3	Tier 3	EXC	X	X	---	---	12/31/23
	Vyvgart Hytrulo (efgartigimod-alf-hyaluronidase-qvfc) SC injection	Brand	Tier 3	Tier 3	EXC	X	X	---	---	12/23/23

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
Antidiabetic Agents	Lantidra (donislecel-jujn) IV injection	Add	12/01/23
Antineoplastic Agents	Ojjaara (mometinib) tablet	Add	12/01/23
Cardiovascular Agents	Lodoco (cochicine) tablet	Add	12/01/23
Cariostatic Agents	Pokonza (potassium chloride) powder packet	Add	12/01/23
Dermatological Agents	cantharidin topical solution	Add	11/17/23
	Ycanth (cantharidin) topical solution	Add	11/17/23

Therapeutic use	Medication name	Add/Remove	Effective date
Hematological Agents	Jesduvroq (daprodustat) tablet	Add	12/01/23
Ophthalmic Agents	Xdemvy (lotilaner) ophthalmic solution	Add	11/01/23
Skeletal Muscle Relaxants	Sohonos (palovarotene) capsule	Add	12/01/23

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.

Therapeutic use	Medication name	Add/Remove	Effective date
Antipsychotic Agents	Rykindo (risperidone ER) IM injection	Add	12/01/23
Ophthalmic Agents	lyuzeh (latanoprost) ophthalmic solution	Add	12/01/23

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
Anti-infective Agents	Beyfortus (nirsevimab-alip) IM injection	Add	11/01/23
Hematological Agents	Jesduvroq (daprodustat) tablet	Add	12/01/23
Ophthalmic Agents	lyuzeh (latanoprost) ophthalmic solution	Add	12/01/23
Skeletal Muscle Relaxants	Sohonos (palovarotene) capsule	Add	12/01/23
Vaccine	Abrysvo (RSV pre-fusion f A&B vaccine recombinant) IM injection	Add	11/01/23
	Arexvy (RSVPREF3 vaccine recombinant) IM injection	Add	11/01/23



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

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