

Medication Trend Updates and Formulary Changes – 3rd Quarter 2023

Review formulary changes and medication safety issues

Stay up to date with information about:

- Patent expiration for commonly used brand-name medication.
- FDA withdrawal of brand Makena and its generics.
- FDA approved over-the-counter Narcan® nasal spray.
- Changes to the Health Net*, on behalf of CalViva Health, commercial Formulary, Medi-Cal Preferred Drug List (PDL) and Medicare Part D Formulary for the third quarter of 2023.

Patent expiration for commonly used brand-name medication

Patents are granted by the United States Patent and Trademark Office along the development lifeline of a medication. Patents expire 20 years from the date of filing. Many factors can affect the duration of a patent. When a brand-name medication loses its patent, lower-priced generics enter the market. U.S. Food and Drug Administration (FDA)-approved generic drugs are made under the same rigorous standards as their brand-name counterparts and are bioequivalent, delivering the same amount of active ingredients into a patient's bloodstream in the same amount of time as their brand-name product. During the upcoming year, the key medications listed below are anticipated to be available as generic equivalents.

THIS UPDATE APPLIES TO:

- Physicians
- Participating Physician Groups

PROVIDER SERVICES

888-893-1569
www.healthnet.com

PROVIDER PORTAL

provider.healthnetcalifornia.com

Medication patent expirations

	2023	2024
1 st Quarter	Aubagio®, Kombiglyze® XR, Latuda®, Onglyza®	Emflaza®, Gralise®, Myrbetriq®, Spiriva® Handihaler, Tasigna®, Vesicare LS®
2 nd Quarter	Livalo®	Duavee®, Dutrebis™, Isentress®
3 rd Quarter	Vyvanse®	Sprycel®
4 th Quarter	Votrient®	Qysmia®, Rydapt®, Siklos®, Stendra®, Vuity®

For formulary coverage, please refer to the Medi-Cal Contract Drugs List at <https://medi-calrx.dhcs.ca.gov/home/cdl/>.

FDA withdrawal of brand Makena and its generics for prevention of preterm birth

On April 6, 2023, the FDA formalized its decision to withdraw approval for Makena and its generics (17-alpha hydroxyprogesterone caproate, 17-OHPC) for the prevention of preterm birth. Makena previously gained FDA approval under the organization's Accelerated Approval Program, whereby the sponsor was required to conduct a postmarket clinical trial to verify the medication's benefit on reducing preterm births. This confirmational study failed to show that the medication reduced the risk of preterm births or resulted in neonatal clinical benefits. As a result, the FDA made the decision to withdraw approval of Makena and its generics.

While the approvals of Makena and its generics have been withdrawn, the FDA has advised patients to talk to their health care provider while recognizing that there is a supply of Makena and its generics that has already been distributed. Covis Pharma, maker of Makena, recommends that health care providers consider the FDA's conclusion on the withdrawal of Makena because Makena and its generics are no longer shown to be effective. Its benefits do not outweigh the risks for the indication for which they were approved. For additional information from the FDA on Makena, please refer to <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information>.

The FDA approved the first over-the-counter (OTC) Narcan nasal spray

On March 29, 2023, the FDA approved Narcan, 4 milligram naloxone nasal spray, for OTC without a prescription. Narcan is a potentially lifesaving medication designed to help reverse the effects of an opioid in minutes. Drug overdose persists as a major public health issue in the United States, primarily driven by synthetic opioids. With the approval of OTC naloxone nasal spray, this will help improve access to naloxone and reduce opioid overdose deaths throughout the country.

The nasal spray will come in a package of two 4-milligram doses in case the person overdosing does not respond to the first dose. The product could be given to known or suspected opioid overdose in adults and children. Emergent BioSolutions, maker of OTC Narcan, expects the product to be for sale in big-box chains, supermarkets, convenience stores, gas stations and online retailers by late summer.

Drug benefit changes

The Pharmacy and Therapeutics (P&T) Committee includes practicing physicians, pharmacists and other health care professionals. Each quarter, the P&T Committee reviews medications on the Formulary for commercial members, the PDL for Medi-Cal members, and the Medicare Part D Formulary for Medicare members to determine which medications remain on the same tier and which are moved. Refer to page 3 for a listing of some recent changes. The list contains brand-name prescription medications, status, other medication choices, and comments for the third quarter of 2023.

The complete lists of the commercial Formularies, Medi-Cal PDLs and Medicare Part D Formularies are available on the Plan provider website as listed below under Additional Information.

Changes to the CalViva Health Medi-Cal drug benefits

Medication	Status	Formulary alternative(s)	Comments
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Injectable preparations

Leqembi™ (lecanemab-irmb)	Medical Benefit ²		An amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.
Zynteglo® (betibeglogene autotemcel)	Medical Benefit ²		Treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions

Intravesical preparations

Adstiladrin® (nadofaragene firadenovec-vncg)	Medical Benefit ²		A non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
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Pharmacy help line

For more information regarding changes to the Medi-Cal medical benefit drugs, contact the proper pharmacy phone number listed.

Product	Phone number	Fax number
Pharmacy Benefit (Medi-Cal Rx)	800-977-2273	800-869-4325
Medical Benefit Drugs (Medi-Cal)	800-675-6110	833-953-3436

Additional information

Providers are encouraged to access the provider portal online at provider.healthnetcalifornia.com for real-time information, including eligibility verification, claims status, prior authorization status, plan summaries, and more.

If you have questions regarding the information contained in this update, contact CalViva Health at 888-893-1569.

²Prior authorization (PA) is required to verify that the member is eligible and satisfies clinical protocols to ensure appropriate use of the medication.