

Medication Trend Updates and Drug List/Formulary Changes – 3rd Quarter 2026

Review drug list and medication benefit changes, and medication safety issues

Stay up to date with information about:

- U.S. Food and Drug Administration (FDA) removal of black box warnings on menopausal hormone therapy.
- Changes to the Medi-Cal medication benefits for the third quarter of 2026.

FDA removal of black box warnings on menopausal hormone therapy

The FDA has approved labeling updates for six menopausal hormone therapy (traditionally referred to as HRT for hormone replacement therapy) products to better reflect current evidence on safety risks. As part of these changes, statements regarding cardiovascular disease, breast cancer and probable dementia were removed from the boxed warning — the FDA’s most prominent safety warning — while related risk information remains elsewhere in the labeling.

The FDA initiated the removal of these warnings in November 2025, following a comprehensive review of scientific literature and the first major reassessment of HRT safety in more than two decades. Despite the removal, the warning for endometrial cancer will remain on systemic estrogen-alone therapies.

According to the FDA, 29 drug companies have submitted proposed labeling changes. This first batch of six products with approved labeling changes includes products from each of the four categories of HRT for menopausal women:

- Systemic combination therapy (estradiol and progesterone):
 - Bijuva® (Mayne Pharma)
- Systemic estrogen-alone therapy:
 - estradiol gel (Divigel®; Vertical Pharmaceuticals),

THIS UPDATE APPLIES TO:

- Physicians and Practitioners
- Participating Physician Groups
- Behavioral Health Providers

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- synthetic conjugated estrogens, A (Cenestin®; Teva Pharmaceuticals), and
- synthetic conjugated estrogens, B (Enjuvia®; Teva Pharmaceuticals)
- Systemic progestogen-alone therapy:
 - progesterone, USP (Prometrium®; Abbott Laboratories), for women with a uterus using systemic estrogen
- Topical vaginal estrogen therapy:
 - estradiol vaginal ring (Estring®; Pfizer)

The FDA added that the update ensures women have clear, science-based information about HRT, supporting informed decisions about their treatment plan for menopause symptoms.

Source: www.fda.gov/news-events/press-announcements/fda-approves-labeling-changes-menopausal-hormone-therapy-products

Changes to Medi-Cal medication benefits

The Pharmacy Advisory Committee is made up of practicing physicians, pharmacists and other healthcare professionals. Every quarter, the committee reviews medication benefits for Medi-Cal members. They decide which medications stay on the same tier and which ones move to a different tier.

A table showing some of the recent changes for **Q3 2026** is available on **page 3**. It includes:

- Medication names.
- Their updated formulary status.
- Formulary alternative options.
- Notes or comments.

You can find the complete drug lists and formularies for all products, including for Medi-Cal, on the Pharmacy Information for Providers page at <https://bit.ly/PharmacyInformationforProviders>.

For medical drug benefits, refer to the *Outpatient Pharmaceuticals (Submitted Under Medical Benefit)* section of the CalViva Health Medi-Cal Fee-for-Service **Prior Authorization List** at <https://bit.ly/HealthNetPriorAuthorizations>.

Pharmacy help lines

For more information regarding changes to the Medi-Cal Drug List or medication benefit, 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)	800-867-6564, option #2	833-953-3436

Need help? Contact us

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

Changes to the Medi-Cal medication benefits

Note: The information in the table is subject to change. For the most current details, please refer to the CalViva Health Medi-Cal Fee-for-Service Prior Authorization List at <https://bit.ly/HealthNetPriorAuthorizations>.

Medication	Status	Formulary alternative(s)	Comments
Topical preparation			
Adquey™ (difamilast) ointment	Carved out to state	Carved out to state	A phosphodiesterase 4 inhibitor indicated for the topical treatment of adults and pediatric patients ages 2 and older with mild to moderate atopic dermatitis.
Injectable preparation			
Awicli® (insulin icodexabae) prefilled pen	Carved out to state	Carved out to state	A long-acting human insulin analog indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Otarmeni™ (lunsotogene parvec-cwaha) suspension, for intracochlear infusion	Medical benefit ¹	Carved out to state	An adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency > 90 dB HL) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.
Yuviwel® (navepegritide) single-dose vial	Medical benefit ¹	Carved out to state	A C-type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients ages 2 and older with achondroplasia with open epiphyses.
Zycubo® (copper histidinate) single-dose vial	Medical benefit ¹	Carved out to state	A copper replacement product indicated for the treatment of Menkes disease in pediatric patients

¹ Prior authorization is required to verify that the member is eligible and satisfies clinical protocols to ensure appropriate use of the medication.