PROVIDER*Update*

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Medication Trend Updates and Formulary Changes – 2nd Quarter 2023

Review formulary changes and medication safety issues

Stay up to date with information about:

- Availability of Humira® biosimilars in 2023.
- Removal of X-Waiver for medications used for opioid use disorder (OUD).
- Changes to the California Health & Wellness Plan (CHWP) Medi-Cal drug benefits for the first quarter of 2023.

Humira biosimilars enter the market in 2023

Several FDA-approved biosimilars of Humira will hit the U.S. market this year. Biosimilars have slightly different structures than the referenced product but demonstrate the same effect in treating a disease. In addition, biosimilars are lower-cost medications than their brand biologics.

Humira is FDA-approved to treat several autoimmune conditions in adult and children including rheumatoid arthritis, Crohn's disease and ulcerative colitis. The Humira biosimilars launching in 2023 are approved for most of the same indications as Humira, with two exceptions. The biosimilars are not approved to treat hidradenitis suppurativa or uveitis. They also vary in their available concentrations and doses as well. One or more of the biosimilars will have the interchangeability designation. An interchangeable biosimilar can be automatically substituted for Humira at a pharmacy without first consulting with the prescribing physician. This will eliminate the need for another prescription.

Most Humira biosimilars are expected to launch in July 2023, but Amjevita was launched on January 31, 2023.

THIS UPDATE APPLIES TO:

- Physicians
- Independent Practice Associations

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Call Us at 877-658-0305

Monday to Friday
8 a.m. to 5 p.m. (PT)

Fax Numbers

Prior Authorizations: 866-724-5057
Concurrent Review: 855-556-7910
Admissions: 855-556-7907
Appeals: 855-460-1009
Case Management: 855-556-7909

Pharmacy
Medi-Cal Rx – Self-administered drugs and supplies obtained under the pharmacy benefit

- Prior auth fax: 800-869-4325
- Help Desk: 800-977-2273

AcariaHealth – Specialty Pharmacy

- Prior auth fax: 855-217-0926
- Phone: 855-535-1815

CHWP Pharmacy Dept – Provider-administered drugs requiring prior auth

- Prior auth fax: 877-259-6961
- Phone: 877-658-0305

Medication Prior Authorization Form is available at www.CAHealthWellness.com.

Humira Biosimilar Brand Products	Anticipated Launch Date	Interchangeability Designation
Amjevita	Launched on January 31, 2023	No
Abrilada	July 2023	Under review
Cyltezo	July 2023	Yes
Hadlima	July 2023	No; expected post-launch
Hulio	July 2023	No
Hyrimoz	July 2023	No
Idacio	July 2023	No
Yusimry	July 2023	No

X-Waiver requirement is removed for all prescriptions used for OUD

On January 12, 2023, the Drug Enforcement Administration (DEA) confirmed in a letter to registrants that Section 1262 of the Consolidated Appropriations Act, 2023 eliminated the DATA-Waiver Program. Effective immediately, waiver applications will no longer be accepted.

All buprenorphine prescriptions now only require a standard DEA registration number. The previously used DATA-Waiver (also known as X-Waiver) registration numbers are no longer needed for any prescription. Any practitioner with a current DEA registration that includes Schedule III authority may now prescribe buprenorphine for OUD in their practice. Prescribers no longer have a limit on the number of patients they can treat for OUD with buprenorphine.

For additional information on the removal of the DATA-Waiver requirement, see the statement issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) website.

Reference: https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement

Drug benefit changes

The CHWP Pharmacy and Therapeutics (P&T) Committee, which includes practicing physicians, pharmacists and other health care professionals, reviews drug benefit decisions each quarter to determine medications to stay on or be moved to a different status. A list of recent changes is provided in the table on page 3. The list contains brand-name prescription medications, status, other medication choices, and comments for the second quarter of 2023.

Pharmacy help line

For more information regarding changes to the CHWP Medi-Cal *Preferred Drug List*, contact the proper pharmacy phone numbers:

Product	Phone number	Fax number
Pharmacy Benefit (Medi-Cal Rx)	800-977-2273	800-869-4325
Medical Benefit Drugs (Medi-Cal)	877-658-0305	877-259-6961

Additional information

Providers are encouraged to access CHWP's provider portal online at www.CAHealthWellness.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 CHWP at 877-658-0305.

Changes to the CHWP drug benefits

Medication	Status	Formulary alternative(s)	Comments
Injectable preparations			
Hemgenix® (etranacogene dezaparvovec-drlb)	Medical benefit*		An adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: • Currently use Factor IX prophylaxis therapy, or • Have current or historical life-threatening hemorrhage, or • Have repeated, serious spontaneous bleeding episodes.
Skysona® (elivaldogene autotemcel)	Medical benefit*		To slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have gadolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9.
Tzield™ (teplizumab-mzwv)	Medical benefit*		A CD3-directed antibody indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D.
Amjevita™ (adalimumab-atto)	Carved out		Biosimilar to the brand Humira®. For commercial, Amjevita is co-preferred with Humira.

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