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Department of Health Care Services



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Medi-Cal Fee-For-Service (FFS) Pharmacy Benefit Section 1135 Waiver Flexibilities Relative to the 2019-Novel Coronavirus (COVID-19)

March 26, 2020

On March 16, 2020 and March 19, 2020, DHCS submitted requests to waive or modify a number of federal requirements under Section 1135 of the Social Security Act (Title 42 United States Code section 1320b-5) to CMS. DHCS' Section 1135 Waiver submission requested various flexibilities as related to the COVID-19 public health emergency. On March 23, 2020, CMS submitted an [approval letter](#) to DHCS summarizing its approval of specific requested Section 1135 Waiver flexibilities.

Based on the March 23, 2020 approval, DHCS is issuing the following guidance relative to temporary flexibilities in dispensing policies governing off-label and investigational use of medications under the Medi-Cal FFS pharmacy benefit, which will be in effect until further notice.

Off-label and investigational use of medications

Currently, Section 1927 of the Social Security Act and Title 22 of the California Code of Regulations limit the use of Food and Drug Administration (FDA)-approved “off-label” and investigational drugs in the Medi-Cal program and require an approved TAR for reimbursement.

According to the Centers for Disease Control and Prevention there are no FDA-approved drugs specifically for the treatment of patients with COVID-19. At present, clinical management includes infection prevention and control measures and supportive care, including supplementary oxygen and mechanical ventilator support when indicated.

An array of drugs, approved for other indications as well as several investigational drugs, are being studied across the globe. Studies so far are mostly small and lack real control groups, making it hard for researchers to be sure of their conclusions. Clinical use of these medications is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of each medical facility's approach to the care of patients with COVID-19 and the needs of individual patients.

Due to the increasingly emergent nature of the impacts of COVID 19, effective immediately, DHCS will cover and reimburse off-label and/or investigational medications

not yet having the required published documentation for use in COVID-19, as listed in Title 22, California Code of Regulations, sections 51303 and 51313. A TAR will not be needed.

Unlabeled and investigational treatment claims for COVID-19 must be billed manually. Specific instructions for submitting claims for both unlabeled use (billed with the National Drug Code (NDC) assigned to the medication), and investigational use (billing code to be determined) will be forthcoming in a separate provider update on COVID-19.

This temporary policy change will end upon the declaration of the end of the COVID-19 emergency, or as soon as a FDA approved treatment for COVID-19 becomes available.

Additional Resources

Any questions regarding this notice may be directed to the Telephone Service Center (TSC) at 1-800-541-5555, Monday through Friday, 8:00 a.m. through 5:00 p.m. except holidays.

For general Medi-Cal information, you can visit the [Medi-Cal website](#), and for COVID-19 specific information, please visit DHCS' [COVID-19 Response webpage](#), which also includes guidance specific to [Medi-Cal FFS pharmacy benefits](#).

For additional COVID-19 information and resources, providers are encouraged to review the following resources:

- [List of California Department of Public Health \(CDPH\) COVID-19 Guidance Documents](#)
- [Centers for Disease Control and Prevention \(CDC\) COVID-19 response](#)
 - [en Español](#)
 - [中文](#)
- [Follow CDPH Twitter for the latest COVID-19 information](#)