Effective Date **3/15/2024**
Next Review Date **3/15/2025**
Coverage Policy Number **IP0370**

Hydroxyprogesterone Caproate

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy addresses the usage of hydroxyprogesterone caproate (**Makena®**).

Effective April 6, 2023, FDA withdrew approval for Makena and its generics. As a result of this withdrawal of approval, Makena and its generics are now unapproved products and cannot lawfully be distributed in interstate commerce.

Conditions Not Covered

The use of hydroxyprogesterone caproate (Makena) is considered to be experimental, investigational, or unproven due to insufficient data establishing safety, efficacy, and improved health outcomes for any condition.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1726	Injection, hydroxyprogesterone caproate, (Makena), 10 mg

Background

OVERVIEW

Makena was an injectable progestin which was indicated to reduce the risk of preterm birth in women with a singleton pregnancy that have a history of singleton spontaneous preterm birth.[1] The effectiveness of Makena was based on improvement in the proportion of women who delivered < 37 weeks of gestation. On April 6, 2023, Makena and its generics were withdrawn from the market. The FDA recognized that a limited supply of the product had already been distributed and advised patients to consult with their healthcare provider.[2]

References

1. Makena® for intramuscular or subcutaneous use [prescribing information]. Waltham, MA: AMAG; December 2022.
2. FDA commissioner and chief scientist announce decision to withdraw approval of Makena [press release]. April 6, 2023. Available at: FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena | FDA. Accessed on April 6, 2023.