



NETWORK *Notification*

Notice Date: May 22, 2023
To: Ohio Medicaid
From: CareSource
Subject: Withdraw Approval of Makena
Effective Date: April 6, 2023

Summary

On April 6, 2023, the U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena. Effective this date, Makena and its generics are no longer approved and cannot be lawfully distributed in interstate commerce. CareSource is committed to supporting and working collectively with our health partners to promote and identify the needs of our pregnant members with the common goal of optimal outcomes for both mom and baby.

Impact

The withdraw of Makena no longer being an available option to patients/members may result in increased risk and concerns for your patients. The managed care plans can follow your patients through our internal programs, benefits, and services. Therefore, if you have previously completed and submitted a Pregnancy Risk Assessment Form (PRAF) as a tool to prescribe Makena, please continue to submit PRAFs, as this presents significant opportunity to allow the managed care plans to better support your patients.

If you have not previously utilized the PRAF tool and would like information and support regarding benefits, reimbursement, and submission, please contact CareSource using the contact information below.

Importance

The benefits of PRAFs are as follows:

- Data is integrated with the Ohio Department of Job and Family Services County Office, Managed Care Plan, Women, Infants & Children (WIC), Statewide Automated Child Welfare Information System (SACWIS), Ohio Department of Health (ODH).
- Information within the PRAF will inform the managed care organization (MCO) and other entities of identified needs including physical, behavioral health and social determinants of health (SDoH) allowing care coordination and services.
- Providers can submit additional PRAFs to report change in condition or needs.
- Pregnant women's Medicaid eligibility is maintained without disruption in coverage-equating to prompt provider payment for services throughout mom's pregnancy.
- Reimbursement rate \$90 for each PRAF is completed and submitted electronically (Nurture).

Contact Information

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