

Notice Date: May 22, 2023
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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. **Effective Date: April 6, 2023**

Center for Disease Control and Prevention, National Center for Human Growth and Development, and the American College of Obstetricians and Gynecologists are withdrawing approval of Makena collectively with our health partners to identify the needs of 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.

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 Information System (SACWIS), Ohio Department of Health (ODH).
- Information within the PRAF will inform the managed care organization (MCO) and of identified needs including physical, behavioral health and social determinants of health (SDoH) allowing care coordination and services.
- Providers can

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