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Subject:	**Drug Management Program (DMP) Policy and Procedure**
Policy Origin Date:	January 1, 2022
Most Recent Revision Date:	
Approving Committee & Date:	Pharmacy and Therapeutics Committee or PACE Medical Director
Part D Regulation:	42 CFR §423.153(f)
Additional References:	• 2021 Part D Drug Management Program Guidance, December 20, 2020 • CY 2021 OMS Technical Guidance (December 2020) • 42 CFR §423.38 Enrollment periods • 42 CFR §423.100 Definitions • 42 CFR §423.580 Right to a redetermination • 42 CFR §423.582 Request for a standard redetermination • 42 CFR §423.584 Expediting certain redeterminations • 42 CFR §423.590 Timeframes and responsibility for making redeterminations • 42 CFR §423.600 Reconsideration by an independent review entity (IRE) • Beneficiary Protections for Qualified Prescription Drug Coverage Sec. 1860D-4. [42 U.S.C. 1395w-104]

PURPOSE

1. To outline guidelines for PACE programs to follow in regards to Medicare Part D Drug Management Program (DMP).

Key of abbreviations used:

- ARB – At-Risk Beneficiary
- DMP – Drug Management Program
- FADs – Frequently Abused Drugs
- IRE – Independent Review Entity
- LIS – Low Income Subsidy-Eligible Beneficiaries
- MARx – Medicare Advantage Prescription Drug (Accessed via mccm.cms.gov)
- OMS – Overutilization Monitoring System (Accessed via Acumen)
- PARB – Potential At-Risk Beneficiary
- SEP – Special Enrollment Period

Definitions:

- ARB: a Part D eligible individual identified using clinical guidelines, not an exempted beneficiary, and determined to be at-risk for misuse or abuse of FADs; or whom was identified as an ARB by most recent Part D plan and such identification had not been terminated upon disenrollment.
- PARB: individual identified using clinical guidelines; or whom was identified as a PARB by most recent Part D plan and such identification had not been terminated upon disenrollment.
- Exempted Beneficiary: with respect to a drug management program, an enrollee who -
  (1) Has elected to receive hospice care or is receiving palliative or end-of-life care;
  (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act,

*All information current as of 7/22/21

or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy;
(3) Is being treated for active cancer-related pain or
(4) Has sickle cell disease.

POLICY

1. [PACE Program] will employ case management for those identified as PARBs, including those participants who are inadvertently reported by OMS to determine whether a PARB is an ARB.
    a. The plan will review all beneficiaries meeting the minimum OMS criteria.
    b. Sources of info: MARx (prior plans who implemented DMP on PARBs) and OMS report
        i. OMS: PARB 1s and ARB 1s
        ii. MARx: PARB 2s and ARB 2s
            1. Exception for identification by prior plan: Plan does not have to engage in case management for PARB 2s and ARB 2s, so long as the PACE plan obtains case management information from the most recent Part D sponsor and such information is still clinically adequate and up to date.
2. [PACE Program] will respond to requests from other sponsors for information about PARBs and ARBs who recently disenrolled and document such communications and transfer of information.
3. Identify potentially at-risk beneficiaries (PARBs) upon enrollment and assess status at least annually
    a. If a beneficiary is determined to be at-risk, after notifying the beneficiary in writing, [PACE program] may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacies and/or through a beneficiary-specific point-of- sale (POS) claim edit (see Appendix A).
4. In general with respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by [PACE program], the plan shall select:
    a. one, or, if reasonably determined necessary to provide the beneficiary with reasonable access, more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a "prescriber") who may write prescriptions for such drugs for such beneficiary; and
    b. one, or, if reasonably determined necessary to provide the beneficiary with reasonable access, more than one, pharmacy that may dispense such drugs to such beneficiary.
        i. In the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.
    c. Reasonable access.—In making the selections under this subparagraph—
        i. a prescription drug plan (PDP) sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, impact on cost sharing, and reasonable travel time; and
        ii. a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.
5. ARBs or PARBs may seek an appeal classified as such regarding denial of service or prescription as it relates to controlled substances. If on consideration through internal appeal process [PACE program] affirms its denial, in whole or in part, the case shall be automatically forwarded to the CMS Part D Appeal Contact for review and resolution. (See Appendix B)
6. Requirements for implementing limitations on an ARB's Access to coverage for FADs may only be done if the PACE plan has done all of the following:

a. Conducted the required case management and updated it, if necessary.
b. Obtained the agreement of at least one prescriber of frequently abused drugs for the beneficiary that the specific limitation is appropriate (except in the case of a pharmacy limitation imposed).
c. Provided the required notices to the beneficiary after case management is completed.

PROCEDURE

1. PARB 1s reported by OMS or identified by the sponsor, and PARB 2s and ARB 2s reported by MARx, will receive case management by the PACE plan.
2. As part of case management, the PACE plan will:
    a. Send written information to the beneficiary's prescribers that the beneficiary is being reviewed as potentially at-risk because the beneficiary meets the OMS criteria due to obtaining opioids from multiple prescribers and/or pharmacies
        i. PACE plan to make 3 outreach attempts to contact prescribers over 10 business days during case management with documentation.
    b. Include in the written information the beneficiary's actual total utilization of opioids and/or benzodiazepines, if available
    c. Elicit information and opinions from the prescribers in writing and verbally, as necessary, about any factors in the beneficiary's treatment that are relevant to a determination whether the beneficiary is an ARB, such as:
        i. Whether the beneficiary is an exempted beneficiary
        ii. Whether the prescribed medications are appropriate, medically necessary, and safe for the beneficiary's medication conditions
        iii. Any other relevant treatment factors
        iv. Agreement, if necessary, as to whether a limitation on the beneficiary's access to coverage of FADs is warranted for the safety of the beneficiary
3. After completion of the required case management, the PACE plan that is intending to limit a beneficiary's access to coverage for FADs must provide an initial written notice to the PARB, unless an exception applies. The Initial Notice does the following:
    a. Notifies the PARB that they have been identified as potentially at-risk for misuse or abuse of FADs, and that the PACE plan intends to limit their access to FADs under its DMP;
    b. Describes the specific coverage limitation(s) the sponsor intends to implement and the timeframe for its decision;
    c. Explains how the PARB or their prescriber can provide additional information if they do not agree with the plan's intended action, including the PARB's preferences for the selected pharmacy and/or prescriber, if applicable;
    d. Provides information about resources and plan benefits designed to address prescription drug abuse;
    e. Explains that the beneficiary will have the right to appeal if the plan determines the beneficiary is at-risk and implements a limitation under the DMP; and
    f. Informs the PARB with LIS of the limitation on the available of the special enrollment period (SEP).
4. When the PACE plan makes a determination that a beneficiary is an ARB and limits the ARB's access to coverage for FADs, the plan must give the Second Notice to the beneficiary, as soon as possible after the end of the beneficiary's 30 day response period, but no later than 50 days from the date of the Initial Notice. The Second Notice does the following:
    a. Notifies the ARB that the sponsor has identified them as at risk for misuse or abuse of FADs, and the that the

   b. Describes the coverage specific limitation(s) the sponsor is implementing, including the effective and end dates and the selected pharmacy and/or prescriber, if applicable;
   c. Explains how the beneficiary can submit preferences for the selected pharmacy and/or prescriber, if applicable;
   d. Explains the beneficiary's right to a redetermination, including the right to an expedited redetermination, and how to request one; and
   e. Informs the ARB with LIS that the limitation on the SEP continues.
5. The effective date of a coverage limitation implemented under a DMP is the date of the Second notice.
6. PACE Plan will use the information they obtained from case management to choose standardized responses in OMS and submit information to MARx about any limitations that the sponsor notified the beneficiary about and implemented for the beneficiary's safety.
7. Termination dates: The identification of an ARB as such must terminate on whichever of the following 2 possible dates is earliest:
   a. The date the beneficiary demonstrates that they are no longer likely to be at risk for abuse or misuse of FADs without the limitation through a subsequent determination, including but not limited to successful appeal; or
   b. The date that is the end of:
      i. The 1 year period calculated form the effective date of the limitation, unless the limitation is extended, or
      ii. The date that is the end of a 2 year period calculated form the effective date of the limitation, if the limitation was extended.

*All information current as of 7/22/21

APPENDIX A- REQUIREMENTS FOR LIMITING ACCESS TO COVERAGE OF FREQUENTLY ABUSED DRUGS (FADs)

Coverage Limitation on FADs	Prescriber Verification Beneficiary is At-Risk**	Prescriber Agreement**** for Coverage Limitation (Initial 12 months)	Prescriber Agreement for Coverage Limitation (Extend Additional 12 months)
Beneficiary-Specific POS Claim Edit	Yes**	Yes**	Yes**
Pharmacy Limitation	Yes**	No*	No*
Prescriber Limitation	Yes***	Yes***	Yes***

*If prescriber rejects a pharmacy limitation, the sponsor should take this into consideration.
**If prescriber does not respond to case management, the sponsor may proceed with this limitation.
***If prescriber does not respond to case management, the sponsor may not proceed with this limitation.

APPENDIX B- STANDARD NOTICES

For drug management program (DMP) appeals plan sponsors may use the DMP Model Redetermination Notice when it has upheld its at-risk determination and is required to send the case file to the IRE for review. The new model notice can be found in the "Downloads" section in the following link: https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments

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