10.8 - Drugs Used to Treat Opioid Dependence

(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)

Part D sponsors must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex®, but must include combination products *that are Part D drugs* when medically necessary (e.g., Suboxone®). For any new enrollees, CMS requires sponsors to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS' non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

A Part D drug is defined, in part, as "a drug that may be dispensed only upon a prescription." Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (**NOTE:** Methadone is a Part D drug when *used* for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.