UC Riverside, School of Medicine Policies and Procedures
Policy Title: Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) Medication Documentation
Policy Number: 950-03-027

Responsible Officer:	Chief Medical Officer
Responsible Office:	Clinical Affairs
Origination Date:	09/2022
Date of Revision:	08/03/2023
Scope:	UCR Health clinical practice sites

I. Policy Summary

This policy provides guideline for compliance with FDA approved risk evaluation and mitigation strategies (REMS) program for Buprenorphine transmucosal products for opioid dependence (BTOD) medication. This policy also covers medication safety processes to mitigate the risks of accidental overdose, misuse, and abuse.

II. Responsibilities

All practitioners

Policy Text [i]

A. Before treatment initiation (first dose)

1. Use the most current version of FDA REMS, BTOD appropriate use checklist: induction section or other means (e.g., electronic medical record) to document that the safe use conditions listed have been completed.
2. If the FDA REMS, BOD appropriate use checklist is used, scan and file to the patient's electronic medical record post encounter.

B. During treatment; at the first visit following induction

1. Prescribe a limited amount of medication.
2. Use the most current version of FDA REMS, BTOD Appropriate use checklist: maintenance section or other means (e.g., electronic medical record) to document that the safe use conditions listed have been completed.
3. If the FDA REMS, BOD appropriate use checklist is used, scan and file to the patient's electronic medical record post encounter.

C. During treatment, at visits scheduled at intervals commensurate with patient stability

1. Use the most current version of FDA REMS, BTOD Appropriate use checklist: maintenance section or other means (e.g., electronic medical record) to document that the safe use conditions listed have been completed.
2. If the FDA REMS, BOD appropriate use checklist is used, scan and file to the patient's electronic medical record post encounter.

III. Forms/Instructions

Access the most current FDA REMS, BTOD appropriate use checklist weblink:
https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=9

IV. Related Information

List of BTOD products covers under FDA REMS[ii]

- Subutex® (buprenorphine) sublingual tablets and generic equivalents.
- Suboxone® (buprenorphine and naloxone) sublingual tablets and sublingual films and generic equivalents
- Zubsolv® (buprenorphine and naloxone) sublingual tablets
- Bunavail® (buprenorphine and naloxone) buccal films
- Cassipa® (buprenorphine and naloxone) sublingual films

Approvals:

COMPLIANCE COMMITTEE (08/22/2023)

DocuSigned by:
Paul Hackman
BC5CF44DC0494EA...

9/1/2023 | 4:01 PM PDT

PAUL HACKMAN, J.D., L.LM.
CHIEF COMPLIANCE AND PRIVACY OFFICER,
SCHOOL OF MEDICINE

DATE

DocuSigned by:
DEBORAH DEAS
870C12B416E84CB...

9/1/2023 | 6:41 PM PDT

DEBORAH DEAS, M.D., M.P.H
VICE CHANCELLOR, HEALTH SCIENCES
DEAN, SCHOOL OF MEDICINE

DATE

[i] FDA approved risk evaluation and mitigation strategies: BTOD summary, US Food and Drug Administration, 2022, May2 (cited 2022, September 7) https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=9

[ii] FDA approved risk evaluation and mitigation strategies: BTOD, US Food and Drug Administration, 2022, May3 (cited 2022, September 7) https://www.accessdata.fda.gov/drugsatfda_docs/rems/BTOD_2022_05_03_Prescriber_Brochure.pdf