Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Probuphine (buprenorphine implant)

CG-DRUG-89

Override(s)	Approval Duration
Prior Authorization	Initial treatment: 6 months Continuation of treatment: 6 additional months Treatment beyond 12 months (1year) is considered investigational and not medically necessary.

Medications
Probuphine® (buprenorphine implant)

APPROVAL CRITERIA

I. Initial treatment with Probuphine* (buprenorphine implant) may be approved when ALL of the following criteria have been met:
   A. The individual has been diagnosed with opioid dependence (opioid use disorder); **AND**
   B. The individual has been treated with a stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments; **AND**
   C. The individual is currently on a maintenance dose** of 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent to achieve sustained prolonged clinical stability on transmucosal buprenorphine; **AND**
   D. Probuphine is used as part of a comprehensive substance use disorder treatment program to include counseling and psychosocial support.

* Initial treatment with Probuphine consists of one 6-month period, involving subdermal placement of the implants in the inner side of the upper arm on one side of the body. Implants must be removed at the end of the sixth month following insertion. If indicated, a second set of implants may be placed in the contralateral arm. The second set of implants should be removed at the end of the second 6 month treatment period.

**The FDA indications specify that maintenance dose should not be tapered to a lower dose for the sole purpose of transitioning to Probuphine.

Probuphine is may **not** be approved for all other indications, including but not limited to:
   A. When the medically necessary criteria above have not been met.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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B. For new entrants to treatment.
C. For individuals who have not achieved and sustained prolonged clinical stability while being maintained on 8 mg per day or less of a sublingual tablet or its transmucosal buprenorphine product equivalent.
D. For individuals not enrolled in a comprehensive substance use disorder treatment program.

Treatment for longer than 12-months with Probuphine may **not** be approved under all circumstances†.

†Individuals can be transitioned back to transmucosal buprenorphine-containing medications for continued treatment after 12 months as needed.

Retreatment with Probuphine after a prior 12-month treatment period may **not** be approved under all circumstances.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Buprenorphine. In: DrugPoints® Evaluations (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated December 5, 2017. Available at: http://www.micromedexsolutions.com. Accessed on March 22, 2018.
2. Gowing L, Ali R, White JM, Mbewe D. Buprenorphine for managing opioid withdrawal. Cochrane Database Syst Rev. 2017;(2):CD002025.
3. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National practice guideline for the use of medications in the treatment of addiction involving opioid use. 2015. Available at: http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24#search="naltrexone". Accessed on March 22, 2018.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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4. Substance Abuse and Mental Health Services Administration (SAMHSA) Buprenorphine Waiver Management. Available at: http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management. Accessed on March 22, 2018.
5. United States Food and Drug Administration. Prescribing information for Probuphine (buprenorphine) implant. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204442Orig1s000lbl.pdf. Accessed on March 22, 2018.