



Final Appraisal Recommendation
Advice No: 0621 – April 2021

**Buprenorphine/naloxone (Suboxone®) 2 mg/0.5 mg,
4 mg/1 mg, 8 mg/2 mg and 12 mg/3 mg sublingual film**

Limited submission by Indivior UK Ltd

Recommendation of AWMSG

Buprenorphine/naloxone (Suboxone®) sublingual film is recommended as an option for restricted use within NHS Wales as substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Suboxone® is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction. In accordance with NICE guidance such treatment should be considered in patients who are unsuitable for maintenance treatment with methadone.

Additional note(s):

- Buprenorphine/naloxone (Suboxone®) sublingual film and buprenorphine/naloxone (Suboxone®) sublingual tablets deliver similar plasma concentrations of buprenorphine but are not bioequivalent. Please refer to the Summary of Product Characteristics for further detail, including guidance on switching between formulations.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4590), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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