

A.7	Bromocriptine and cabergoline – hyperprolactinaemia – EML
Draft recommendation	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Not recommended Justification: Although the conditions that need the proposed medications are rare, yet it is currently still the recommended treatment for the condition. Therefore, the availability of these medications is essential for treatment of the conditions.
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Prevalence and incidence of prolactinomas are approximately 50 per 100,000 and 3–5 new cases/100,000/year. ¹
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Bromocriptine has been used for treatment of hyperprolactinemia since 1970 while cabergoline is currently considered the first-choice drug for the treatment of prolactinomas. ²
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:

¹ Chanson P, Maiter D. The epidemiology, diagnosis and treatment of Prolactinomas: The old and the new. Best Pract Res Clin Endocrinol Metab. 2019 Apr;33(2):101290. doi: 10.1016/j.beem.2019.101290. Epub 2019 Jul 10. PMID: 31326373

² Glezer A, Bronstein MD. Hyperprolactinemia. 2022 Jan 5. In: Feingold KR, Anawalt B, Blackman MR, Boyce A, Chrousos G, Corpas E, de Herder WW, Dhatariya K, Dungan K, Hofland J, Kalra S, Kaltsas G, Kapoor N, Koch C, Kopp P, Korbonits M, Kovacs CS, Kuohung W, Laferrère B, Levy M, McGee EA, McLachlan R, New M, Purnell J, Sahay R, Singer F, Sperling MA, Stratakis CA, Trencle DL, Wilson DP, editors. Endotext [Internet]. South Dartmouth (MA): MDTText.com, Inc.; 2000–. PMID: 25905218.

Are there any adverse effects of concern, or that may require special monitoring?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: A 2018 meta-analysis including 836 cabergoline-treated hyperprolactinemic patients and 1388 healthy controls from 13 published studies and there was an increase in tricuspid regurgitation of any degree. ³
Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: British Society of Echocardiography, the British Heart Valve Society and the Society for Endocrinology recommend that a standard transthoracic echocardiogram should be performed before a patient starts DA therapy for hyperprolactinemia, repeating this exam at 5 years after starting cabergoline in patients taking a total weekly dose less than or equal to 2 mg, or annually if the dose is greater than 2 mg a week. ⁴
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: In the U.S. and most countries around the world, both bromocriptine and cabergoline are generic.
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Has been approved by FDA, EMA, Australian Government, Health Canada, Japanese PMDA. Cabergoline is currently included in the EML of 27 countries, including some LMICs. ⁵

³ Stiles CE, Tetteh-Wayoe ET, Bestwick J, Steeds RP, Drake WM. A meta-analysis of the prevalence of cardiac valvulopathy in hyperprolactinemic patients treated with Cabergoline. J Clin Endocrinol Metab. 2018

⁴ Steeds R, Stiles C, Sharma V, Chambers J, Lloyd G, Drake W. Echocardiography and monitoring patients receiving dopamine agonist therapy for hyperprolactinaemia: A joint position statement of the British Society of Echocardiography, the British Heart Valve Society and the Society for Endocrinology. Clin Endocrinol (Oxf). 2019;90:662–669.

⁵ <https://global.essentialmeds.org/dashboard/medicines/262>

24th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

<p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: https://www.who.int/publications/who-guidelines)</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> Not applicable</p> <p>Comments: Currently no WHO guideline for the conditions.</p>
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