

Vaginal Pessaries for Pelvic Organ Prolapse or Stress Urinary Incontinence: Recommendation

Final Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory
 Committee, recommends publicly funding vaginal pessaries for people with pelvic organ prolapse or stress urinary incontinence

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment¹ and determined that vaginal pessaries may improve outcomes important to people with pelvic organ prolapse or stress urinary incontinence, including incontinence, sexual function, and quality of life, but there is some uncertainty. The evidence supported that people treated with a vaginal pessary had improvements in outcomes at 1- to 2-year follow-up that were similar to other conservative or surgical treatments, and that using a pessary is likely cost-effective. Because of this, the committee concluded that vaginal pessaries are a reasonable alternative for people who may prefer to avoid or defer surgery or are unable to use or access other treatments. The Ontario Health Technology Advisory Committee took into account the lived experience of patients with symptomatic pelvic organ prolapse and/or stress urinary incontinence. Patients described how symptoms led to social isolation, negative body image, and a reduced quality of life. Patients also reported a preference for having non-surgical treatment options to manage symptoms.

Public Comment: February 4 to 24, 2021

Decision Determinants for Vaginal Pessaries for Pelvic Organ Prolapse or Stress Urinary Incontinence

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	Effectiveness How effective is the health technology/intervention likely to be (taking into account any variability)?	Measured with the Urinary Symptom Profile questionnaire, pessaries significantly improved symptoms of stress urinary incontinence (SUI) compared with no treatment. Compared with pelvic floor muscle training (PFMT), there was no significant difference in improvement of long-term symptoms or patient satisfaction.
		For the treatment of symptomatic pelvic organ prolapse (POP), pessary plus PFMT significantly improved symptoms compared with PFMT alone for some symptom scale scores with up to 12-mo follow-up. Similarly, pessary plus PFMT conferred significant improvement in some scores compared to PFMT plus feedback/electrical stimulation/lifestyle advice at 12- and 24-mo follow-up. There was also a significant improvement in sexual function scores for people treated with pessaries plus PFMT over PFMT plus feedback/electrical stimulation/lifestyle advice at 3, 12, and 24 mo.
		In all studies, pessary and comparator treatment groups showed significant within-group improvement in most outcomes despite a nonsignificant difference between the two treatment arms.
		The overall certainty of the evidence for these outcomes was low to very low.
	Safety How safe is the health technology/intervention likely to be?	Pessaries may result in a small increase in adverse events (e.g., vaginal discharge, irritation, or erosion of vaginal wall). The overall certainty of the evidence for adverse events is very low.



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	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	Prevalence of POP among women who have given birth is 50%. Prevalence for nulliparous women (women who have not given birth) is 1.6%. Approximately 1.8 million adult women in Ontario have POP. About 50% of women with urinary incontinence report SUI as the primary or sole symptom of incontinence. Approximately 870,000 adult women in Ontario have SUI.
	Need How large is the need for this health technology/intervention?	Vaginal pessaries are an alternative for people who do not want or are unable to use or undergo other treatment options (e.g., PFMT or surgery). Symptoms of SUI or POP may lead to social isolation and they may negatively affect body image, quality of life, and ability to perform day to day activities.
Patient preferences and values How likely is adoption of the health technology/intervention to be congruent with patient preferences and values and with ethical or legal standards?	Patient preferences and values Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment? (Note: The preferences and values of family members and informal caregivers are to be considered as appropriate.)	Patients reported a preference for having a non-surgical treatment option such as a pessary available.
	Autonomy, privacy, confidentiality, and/or other relevant ethical principles as applicable Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment? (Note: The preferences and values of the public are to be considered as appropriate.)	Providing people with a choice of different effective and cost-effective treatment options for POP and SUI may support patient autonomy and preferences for care.



Decision Criteria	Subcriteria	Decision Determinants Considerations
Equity and patient care How could the health technology/ intervention affect equity of access and coordination of patient care?	Equity of access or outcomes Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?	At the time of this analysis, pessaries for SUI or POP are not publicly funded. Many people with POP and/or SUI do not have a supplementary insurance plan to help with the cost of the device. People who cannot afford to purchase a pessary may experience improved access to this treatment as well as improved outcomes if pessaries were publicly funded.
	Patient care Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?	A pessary can improve health outcomes for patients. The availability of less-invasive options can result in the avoidance of surgery and its associated risks. Challenges to accessing a pessary may be reduced if pessaries are publicly funded because health providers may offer pessaries as an option and may offer different types of pessaries for patients to choose from. Currently, not all health care providers offer the same type or choice of pessaries.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	Pessaries are likely to be cost-effective when used before surgery. A pessary is a cost-effective treatment when surgical treatment is not an option.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	Economic feasibility How economically feasible is the health technology/intervention?	At the time of this analysis, people with SUI or POP wishing to use a pessary must purchase the device out of pocket. Funding pessaries over the next 5 years would cost an additional \$0.3 million to \$0.5 million annually for POP, and \$0.2 million to \$0.3 million annually for SUI.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Ontario has a few pessary clinics within hospitals; however, the majority of pessary treatments are provided at community-based clinics. Currently, there is no centralized purchasing for pessary devices for community-based clinics.

Abbreviations: PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; SUI, stress urinary incontinence.



Reference

(1) Ontario Health. Vaginal pessaries for pelvic organ prolapse or stress urinary incontinence: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2021 May;21(3):1–155. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/vaginal-pessaries-for-pelvic-organ-prolapse-or-stress-urinary-incontinence

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