

BOTTOM LINE: Docusate has now been listed as non-formulary in Alberta Health Services (AHS) and should not be supplied. Patients at risk of experiencing constipation should receive effective laxative therapy.

Background:

Docusate sodium and docusate calcium for constipation have been removed from the AHS Provincial Drug Formulary and Supplements. The utility of stool softeners have not been proven. A review of the evidence and a Canadian consensus statement concluded that docusate is no more effective than placebo in the prevention or management of constipation.^{1, 2}

Docusate is not absorbed systemically and does not interact with receptors in the gastrointestinal tract. Withdrawal or rebound effects are not a concern.³ For patients currently receiving docusate, docusate may be stopped without tapering, additional monitoring, or the need to replace it with another laxative.

- Docusate for the prevention of constipation should be removed from all existing order sets.
- New orders for docusate should not be filled.
- Admitted patients already using docusate should be assessed for discontinuation. Non-formulary processes apply (consult your Zone's low cost non-formulary process).

Unless clinically necessary, patients with spinal cord injury/neurogenic bowel should not have their bowel routines altered (including stopping docusate) without consultation.⁴

Best Practices for the Prevention of Constipation⁵:

Assess patient for symptoms of constipation and whether therapy is required	Difficulty passing stool Incomplete passage of stool Reduced frequency of bowel movements (< 3x/week) Alarm symptoms that warrant further investigation: Change in bowel habits after 50 years of age Blood in stool Weight loss of 5 kg or more in past six months Anemia Family history of colon cancer Refractory constipation
Evaluate for underlying causes of constipation and assess for alternative therapies	Medications: anticholinergics, opioids, calcium channel blockers, beta-blockers, iron supplements Disease states: anxiety, autonomic neuropathy, chronic kidney disease, colorectal cancer, dementia, depression, diabetes, diverticulitis, hemorrhoids, hypercalcemia, hypokalemia, hypothyroidism, irritable bowel syndrome, multiple sclerosis, Parkinson disease, rectal prolapse, stroke, systemic sclerosis/scleroderma
Prevention of constipation *Consider referral to dietitian	Non-pharmacologic interventions: dietary fibre , hydration, increase physical activity, Bulk Forming: psyllium (avoid if patient has difficulty swallowing, is fluid restricted, or is immobile. Avoid in patients with upper spinal cord injuries)
First line options *if known or suspect intestinal obstruction – avoid oral laxatives	PEG 3350 (first choice in post-operative and post myocardial infarction patients) Lactulose
Second Line options: Stimulants *risk of dependence is low	Sennosides Bisacodyl

Frequently Asked Questions

Why is docusate being removed from the formulary?

The AHS Provincial Drug Formulary is built upon the principles of safety, efficacy and sustainability. In studies where docusate has been compared to placebo, its efficacy for the prevention and treatment of constipation is the same. There are significant operational resources allocated to the procurement, distribution and administration of docusate.

Isn't this going to be a lot of work for little financial return?

AHS's purchases for docusate in 2015/16 were \$29,000, which equated to over 500,000 doses. This does not take into account the time for nursing to administer the drug and Pharmacy Services workload for order entry, shelf space, packaging and inventory management. The best estimates allocate 45 seconds for a nurse to administer a medication dose, so there are at least 6250 hours of nursing time spent on docusate every year.

What has been done so far?

Following the publication of the [Stool Softeners: Why are the still used? Drugs & Therapeutics Backgrounder](#) in December 2014, [a 39% relative reduction in docusate occurred across AHS](#). In October 2016, [the AHS Drugs & Therapeutics Committee \(DTC\)](#) decided to delist docusate for constipation (docusate liquid remains formulary for use as a ceruminolytic). Due to the extent that docusate is included on order sets, the deadline for moving docusate to non-formulary status is October 31, 2017.

What do you want me to do?

- It is safe to stop docusate and not replace it with another medication, if the patient is assessed for constipation risks.
- Patients presenting on docusate: Assess patient for constipation. Have therapeutic conversation with prescriber to discontinue docusate. If patient requires laxative therapy, then recommend formulary medication as appropriate.
- For new docusate prescriptions: Assess patient for constipation risks. Have therapeutic conversation with prescriber to use a formulary medication, if required. If unable to stop docusate prescription, utilize your Zone's low cost non-formulary process.
- If you identify a pre-printed form or order set that contains docusate: Work within your teams to initiate a review of the form to have docusate removed.
- Current electronic medication ordering processes (CPOE) should be reviewed to:
 - Remove docusate from the medication selection lists,
 - Remove docusate from electronic order sets, or
 - Add/edit electronic docusate decision support statements on lack of therapeutic effect to discourage use.

What do I tell my patients?⁶

Alberta Health Services strives to provide the best patient care possible. With limited resources, we are constantly reviewing the medications we provide to ensure that they are safe, effective and affordable. Docusate for prevention of constipation is no longer being provided, as medical research has shown that stool softeners do not work and there are more effective options.

Constipation may be caused by medical conditions, medication, the types of food you eat, lack of physical activity, or other causes. Unless contraindicated, [increasing dietary fibre](#) and fluid intake is a reasonable first step.

The Canadian Agency for Drugs and Technology in Health has provided an [Alternative Prescription Pad Tool](#) to assist in patient counselling.

Who else is involved in the docusate delisting process?

The Digestive Health Strategic Clinical Network (SCN) has co-authored these support documents. These will be shared with professional associations (e.g. Colleges of Pharmacy, Medicine and Nursing) to decrease the amount of docusate used in the community. Forms Management has identified pre-printed forms that include docusate, and the authors will be asked to remove it.

References

1. Dioctyl Sulfosuccinate or Docusate (Calcium or Sodium) for the Prevention or Management of Constipation: A Review of the Clinical Effectiveness. CADTH Rapid Response Report. Published June 26, 2014.
2. Paré, Pierre et al. "Recommendations on chronic constipation (including constipation associated with irritable bowel syndrome) treatment." *Canadian Journal of Gastroenterology* 21.Suppl B (2007): 3B.
3. MedFacts. Meta-analysis covering adverse side effect reports of colace capsules (docusate sodium) patients who developed drug withdrawal syndrome. [http://medsfacts.com/study-colace%20capsules%20%20\(docusate%20sodium\)-causing-drug%20withdrawal%20syndrome.php](http://medsfacts.com/study-colace%20capsules%20%20(docusate%20sodium)-causing-drug%20withdrawal%20syndrome.php) (accessed online April 11, 2014)
4. King, RB et al. "Neurogenic Bowel Management in Adults with Spinal Cord Injury". Spinal Cord Injury Clinical Practice Guidelines 1998.
5. Adapted from Canadian Pharmacist's Letter 2016; 32(9):320934
6. Stool Softeners: Alternative Prescription Pad. CADTH Evidence to Use in Primary Care November 3, 2016. Accessed online February 3, 2017 (<https://www.cadth.ca/evidence-bundles/evidence-use-primary-care>)