

Bumetanide Access Through the Exceptional Access Program (EAP) During COVID-19

APRIL 24, 2020

Brand name: Burinex® (Bumetanide)
1 mg tablet. DIN 00728284
5 mg tablet: DIN 00728276

BACKGROUND

Furosemide (Lasix®), is standard treatment and commonly used for patients with heart failure (HF) to help prevent or treat fluid accumulation. The absorption of Lasix is only about 50% of the oral dose under ideal conditions and is highly variable. Therefore, Lasix may become less effective over time in patients with worsening fluid accumulation because of the variable absorption and require this medication to be given intravenously in a hospital setting.

Bumetanide (Burinex®), is a more potent diuretic than Lasix. Bumetanide has a predictable well over 80% absorption rate and the high absorption rate is maintained even in patients with edema. Bumetanide has been used, not infrequently, to help prevent the need for intravenous Lasix. It has been prescribed in selected patients enrolled in multidisciplinary HF clinics in Ontario for over 10-15 years. Similar to Lasix, the dose of Bumetanide is individualized, with monitoring of patient response. However, the cost of Bumetanide is a key barrier to access as it is not covered by the Ontario Drug Benefit program.

Although Bumetanide is available in Ontario through the Exceptional Access Program (EAP); this process can take 4-6 weeks. In the setting of COVID-19, timely access to Bumetanide is critical to support those patients with HF who are refractory to escalating doses of traditional oral diuretic therapy.

In response to a request from Dr. Heather Ross, Dr. Robert McKelvie and CorHealth Ontario to facilitate timely access to Bumetanide during the COVID-19 pandemic, the Ministry of Health has elevated the priority of EAP applications for Bumetanide to Priority 1 Status.

As such, EAP applications for Bumetanide for patients with HF and ongoing fluid overload despite escalating doses of traditional oral diuretic therapy will have a turn around time of 3 business days.

Please see below for additional information from the EAP program regarding the application process. A sample of an application form with suggested language can be access <https://corhealthontario.ca/EAP-application-form-example-for-oral-diuretic-resistance-request.pdf>

If there are any concerns or challenges with your application during COVID-19, please feel free to contact either Margaret Wong (margaret.s.wong@ontario.ca) or Andrew Cornacchia (Andrew.Cornacchia@ontario.ca), co-managers in the EAP at the MOH.

ADDITIONAL INFORMATION REGARDING THE EAP APPLICATIONS

For the requests that are being sent to EAP, the following information is necessary:

- The purpose for which bumetanide is being used and if it is not the indication for which there is a Health Canada notice of compliance, further clinical detail including published evidence for the use in the requested circumstance would need to be provided.

The indication which we consider is: for the treatment of edema associated with congestive heart failure, cirrhosis of the liver and renal disease including nephrotic syndrome

- Information that should be included with the request include:
 - o Treatments that have been used and particularly addressing why furosemide and furosemide used in combination with other funded drugs for edema in the specific clinical circumstance is not appropriate.
 - o Include the dose/dose regimen and if the maximal doses of oral furosemide not tried, provide reasons.
 - o Adverse effects to treatment. If a patient experienced intolerance should describe the severity of the intolerance. Include a description of allergic reactions to furosemide as applicable.

If a request is submitted by the general practitioner, they may include the consultation notes from a specialist if they would facilitate the request information.

WAYS TO SUBMIT AN EAP APPLICATION

1. Using the Special Authorization Digital Information Exchange (SADIE) web portal

Prescribers may submit requests through our Special Authorization Digital Information Exchange (SADIE) web portal. A link to the instructions is provided below. They only need to set themselves up once on the portal. These requests are turned around more quickly than faxing to EAP. This allows you to transfer private health information securely to the Exceptional Access Program in light of changes to how prescribers may be seeing their patients within the current situation.

Information for prescribers about logging into SADIE can be found on the MOH website at:

http://www.health.gov.on.ca/en/pro/programs/sadie/training/docs/prescriber_user_guide.pdf

2. Submitting by FAX

The standard EAP “generic” application form can also be used and directly faxed to the EAP can be found at the following link and the clinical information/existing note can be attached with the request if necessary.

<http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/FormDetail?OpenForm&ACT=RDR&TAB=PROFILE&SRCH=&ENV=WWE&TIT=eap&NO=014-4406-87>

3. Hospital discharge line for patients in hospital

If the patient is in hospital and imminently awaiting discharge, the prescriber can submit the request to the hospital discharge line using the hospital discharge

<https://corhealthontario.ca/Hospital-discharge-form-June-2015-final.pdf>

A reimbursement coordinator or delegate can assist the prescriber with this application but the prescriber needs to sign (e.signature is acceptable) to validate the information submitted.