



Re: Sacubitril/valsartan (Entresto®) reimbursement

3rd December 2020

Dear Colleagues,

As you are aware, sacubitril/valsartan (Entresto®) 24mg/26mg, 49mg/51mg and 97mg/103mg film-coated tablets are approved for reimbursement under the Community Drug Schemes. Due to the significant budget impact associated with this medicine, the HSE introduced an online reimbursement application system, where clinicians are required to apply for reimbursement approval on an individual patient basis. To date over 5,250 online applications have been submitted. I would like to take this opportunity to thank you for your cooperation with this process.

Following a review of the online system, clinicians now have **one** opportunity to submit an online application on behalf of each individual patient. In the case of a negative reimbursement recommendation, an appeal can be sent directly to the HSE-Medicines Management Programme (MMP) at mmp@hse.ie, addressing the rejection reason(s) and outlining any additional information.

In response to feedback received, I would like to highlight that reimbursement applications should be made by the **clinician responsible for the initiation of treatment** due to the information required to be submitted as part of an application. Following the submission of an application, clinicians will have immediate visibility whether the patient has received approval for reimbursement of sacubitril/valsartan under the Community Drug Schemes.

To be eligible for reimbursement of sacubitril/valsartan patients must meet the following criteria at the time of application:

- Left ventricular ejection fraction of $\leq 35\%$
- Symptomatic with NYHA functional class II to IV symptoms
- Receiving optimal medical therapy for heart failure (HF) including an angiotensin converting enzyme inhibitor or an angiotensin II receptor blocker (and other HF therapies including a beta-blocker and mineralocorticoid receptor antagonist as necessary)
- Systolic blood pressure ≥ 100 mmHg
- Serum potassium ≤ 5.4 mmol/L.

Further information is contained in the document *Sacubitril/Valsartan Clinical and Reimbursement Information* which is available on the MMP's website www.hse.ie/yourmedicines.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Professor Michael Barry,
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HSE-Medicines Management Programme.
www.hse.ie/yourmedicines