

## HISTORICALLY ACCEPTED USE

### Tertiary and Quaternary Committee

#### Executive Summary

<p><b>Date:</b> March 2022</p> <p><b>Medicine (INN):</b> High dose (80mg) atorvastatin</p> <p><b>Medicine (ATC):</b> C10AA05</p> <p><b>Indication (ICD10 code):</b> Familial Hypercholesterolemia (E78.0)</p> <p><b>Patient population:</b> Patients with familial hypercholesterolemia not controlled by simvastatin 40mg.</p> <p><b>Prevalence of condition:</b> Subset of familial hypercholesterolemia not controlled by simvastatin 40mg. Estimated to be approximately 500 patients (estimate based on patients currently treated at lipid clinics)</p> <p><b>Level of Care:</b> Tertiary and Quaternary</p> <p><b>Prescriber Level:</b> Specialist (lipid clinic)</p> <p><b>Current standard of Care:</b> Hospital level – standard dose HMG-CoA reductase inhibitors</p> <p><b>Efficacy estimates:</b></p> <ul style="list-style-type: none"> <li>• Cochrane Review: LDL-cholesterol: percentage change with 80mg/day atorvastatin compared with placebo: -51.7 (95% CI -52.2 to -51.2) [high quality evidence]<sup>1</sup></li> </ul>
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#### Historically accepted use Criteria

Criteria		Comment	
1	The medicine is included in the WHO Model Essential Medicines List, either as a core or complementary item, for the indication requested.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
		*low dose included	
2	The medicine is currently registered by SAHPRA for the indication.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
3	There is evidence of long-established (prior to 1996*) safe and effective use of the medicine for the recognised indication in the public health sector.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		Comment: initial trials - 1995 <sup>2</sup> , 1996 <sup>3</sup> , 1997 <sup>4</sup>	
4	New safety or efficacy concerns.	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
		Comment:	
5	Budget impact is <u>not</u> expected to have an incremental increase, that a de novo review is justified.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		Cost of monthly treatment at 80mg/month: R24.71*	
		*MHPL – March 2022, 40mg Atorvastatin, 30s.	
		<b>SEE ANNEXURE A</b>	
6	Equitable access across the country is essential, and is limited only by the availability of adequately trained staff and availability of equipment.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		Comment:	

\* The Essential Drugs Programme (EDP) of South Africa was established in terms of the National Drug Policy (NDP) which was implemented in 1996

## RECOMMENDATION

It is recommended that high-dose atorvastatin (80mg/day) be included on the Tertiary and Quaternary Essential Medicines list for the management of familial hypercholesterolemia in patients attending lipid clinics.

## ANNEXURE A – cost consideration

80mg Atorvastatin dosing	Product	Price*	Cost per patient per month	Cost per patient per year	Potential Budget impact per year (500 patients)
	Atorvastatin; 40mg; Tablet; 30 Tablets	R24.71	R49.42	R593.04	R296,520.00

*\*Potential budget impact is expected to be less, as patients are already being treated at lipid clinics with 80mg atorvastatin.*

40mg simvastatin dosing	Product	Average price*	Cost per patient per month	Cost per patient per year	Potential Budget impact per year (500 patients)
	Simvastatin; 20mg; Tablet; 28 Tablets	R8.25	R16.51	R198.08	R99,040.00

Incremental cost increase from simvastatin 40mg to Atorvastatin 80mg	
Incremental cost increase per patient per month	R32.91
Incremental cost increase per year	R394.96

Budget impact for incremental increase (500 patients) per year	
R197,480.00	per year

## REFERENCES

<sup>1</sup> Adams SP Tsang M, Wright JM. Atorvastatin for lowering lipids (Review). Cochrane Database of Systematic Reviews, 2015 (3), CD008226.

<sup>2</sup> Nawrocki\_JW, Weiss\_SR, Davidson\_MH, Sprecher\_DL, Schwartz\_SL, Lupien\_PJ, et al. Reduction of LDL cholesterol by 25% to 60% in patients with primary hypercholesterolemia by atorvastatin, a new HMG-CoA reductase inhibitor. *Perfusion* 1996;9(3):109-14.

<sup>3</sup> R G Bakker-Arkema 1, M H Davidson, R J Goldstein, J Davignon, J L Isaacsohn, S R Weiss, L M Keilson, W V Brown, V T Miller, L J Shurzinske, D M Black Efficacy and safety of a new HMG-CoA reductase inhibitor, atorvastatin, in patients with hypertriglyceridemia. *JAMA*. 1996 Jan 10;275(2):128-33.

<sup>4</sup> Bakker-Arkema RG. Best J, Fayyad R, Heinonen TM, Mararis AD, Nawrocki JW, Black DM. Review Article: A brief review paper of the efficacy and safety of atorvastatin in early clinical trials. *Atherosclerosis*. 1997, 131: 17-23.