Impact of the Assessment of Medical Benefit (ASMR) Changes on List Prices: *An analysis of HAS re-evaluations*

AUTHORS

Xiao Wei Zhu
Senior Consultant, Alira Health
xiaowei.zhu@alirahealth.com

Clara Bordoy
Senior Consultant, Alira Health
clara.bordoy@alirahealth.com

Oscar Dumoulin
Former consultant, Alira Health

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OBJECTIVES

> Identify the products that experienced a different result in drug's effectiveness rating (ASMR) after a Transparency Committee (TC) re-evaluation

> Assess if and to what extent an ASMR change affects the list price of products

METHODOLOGY

> All re-evaluations published on the HAS website from January 2017 to March 2023 were extracted from explore.data.gouv to isolate products exhibiting distinct ASMR outcomes before and after re-evaluation

> The list price of products with an ASMR change was retrieved from NAVLIN database. It was assumed that any change in list price occurring within 12 months after the re-assessment might be attributed to the ASMR change. However, it is important to note that other market events, such as competitor and generic entry, price reviews, rebated price etc., might trigger a price review

RESULTS

> A drug re-evaluation by the TC happens when new available evidence concerning the product's therapeutic use and the public health need is available. It can be done upon request of the pharmaceutical company or the HAS

> Out of 212 re-evaluations, 30 products experienced a change in ASMR
  - 19 (63.3%) had an increase in their ASMR, while 11 (36.6%) had a decrease
  - 60% of the products belong to the oncology therapeutic area

> Out of the 30 products, only 6 had a change in their list price within 12 months following the re-evaluation

> Two products were excluded because of its (i) diagnostic and (ii) indication expansion nature. Therefore, four products (Figure 1) were identified with a change in their list price after receiving a different ASMR outcome (Table 1).
  - All four products received a decrease in price, which was consistent with the magnitude of change in ASMR rating
  - Myozyme® and Tysabri® had more than one re-evaluation because the TC explicitly requested additional evidence within a pre-specified time period

Figure 1: Inclusion/Exclusion Funnel

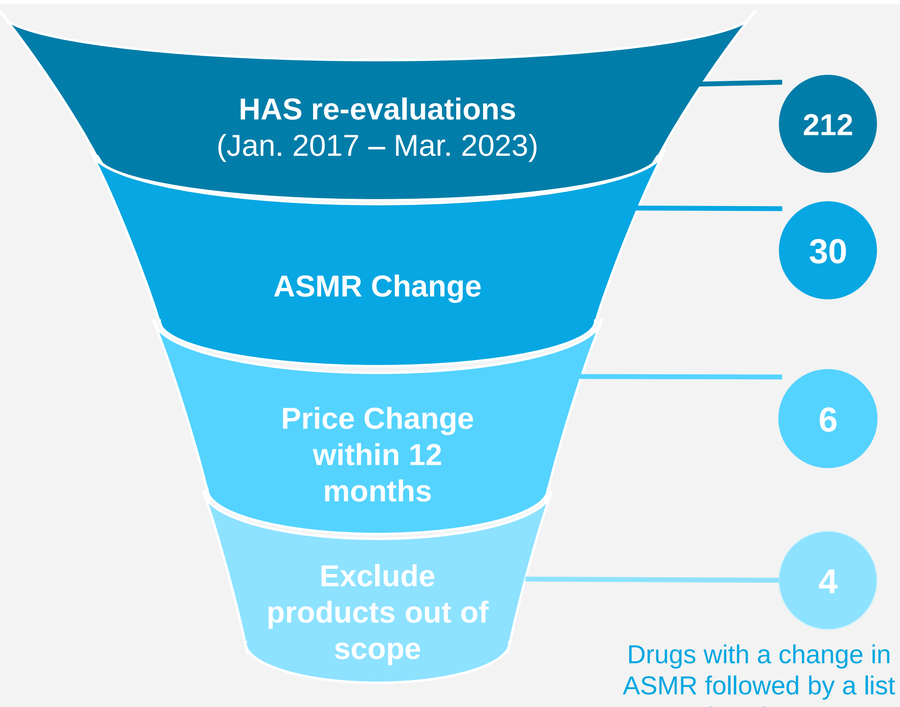

Table 1: List of Products with an ASMR Change and List Price Impact after re-evaluation

Product *(Active Ingredient)*	Therapeutic Area and Indications	Year and ASMR Initial assessment	Year and ASMR re-evaluation	Reason for re-evaluation	Additional Evidence Provided	Ex-MNF List Price/per Pack Change Within 12 Months of re-evaluation
LEVACT® *(bendamustine hydrochloride)*	**Oncology**	**2010**	**2016**	**New competitor entry** affecting the therapeutic positioning in CLL and NHL indications	> Follow-up Study > German patient registry > Observational / non-comparative Study	1369.05 € → 821.44 € *(2016 → 2017)* **-40%**
	> Chronic lymphocytic leukaemia	III	V			
	> Non-Hodgkin's lymphoma	III	V			
	> Multiple myeloma	V	V			
MYOZYME® *(alpha aglucosidase)*	**Metabolic / Rare Disease**	**2006**	**2017**	**Request of the TC** to reassess Myozyme® for both infantile onset and late-onset Pompe	> Two non-comparative studies (infantile onset) with follow-up data > One comparative study vs. placebo (late onset)	525.00 € → 474.60 € *(2017 → 2018)* **- 10%**
	> Pompe disease (infantile onset)	II	III			
	> Pompe disease (late onset)	IV	IV			
TYSABRI® *(natalizumab)*	**Central Nervous System**	**2007**	**2018**	**Request of the TC** for post-registration studies anticipating the arrival of new drugs	> Meta-analysis of indirect comparisons > Non-comparative observational studies	1636.85 € → 1473.17 € *(2018 → 2019)* **-10%**
	> Multiple Sclerosis	III	IV			
VOTRIENT® *(pazopanib)*	**Oncology**	**2013**	**2019**	**New competitor entry** for one of the indications (ARCC)	> One Phase 3 study > Two retrospective analysis	1314.45 € → 1183.01 € *(2019 → 2020)* **-10%**
	> Advanced renal cell carcinoma	IV	V			
	> Certain forms of soft tissue sarcoma	IV	V			

CONCLUSION

> Reasons for TC re-assessments are multiple with the main one being new evidence regarding safety data or vs. an appropriate comparator. In the majority of the cases (+60%), the re-assessment was requested by the TC

> Overall, 63.3% of the products with a change in the drug's effectiveness rating received a better ASMR outcome. The 4 identified products with a change in list price received an ASMR decrease

> The findings of this research suggest that while some products experienced a change in ASMR after a re-evaluation by the HAS, only a small proportion of products show an adjustment in the list price, and this adjustment is always a decrease in price

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