Budget Impact of Subcutaneous Immunoglobulin, Intravenous Immunoglobulin, and Efgartigimod Alfa in Patients With Chronic Inflammatory Demyelinating Polyneuropathy in the United States

Mallick R, CSL Behring, King of Prussia, PA, USA; Carlton R, Cencora, Conshohocken, PA, USA; van Stiphout J, Cencora, Bern, Switzerland; Hubsch A, CSL Behring, Bern, Switzerland, PA; Lahue B, Alkemi, Manchester Center, VT, USA

Introduction

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare, progressive autoimmune disease causing peripheral nervous system dysfunction.[1]
- Subcutaneous immunoglobulin (SCIG) or intravenous immunoglobulin (IVIG) therapy are recommended as first line immunomodulatory agent in CIDP.
- Efgartigimod alfa, a novel FcRn antagonist, is expected to become available as an additional option for CIDP patients.

Objective

- To estimate the budget impact of efgartigimod alfa in a proportion of CIDP patients currently receiving SCIG and IVIG.

Methods

- A budget impact model was developed to project, from a US integrated delivery network perspective, the costs expected with efgartigimod alfa for CIDP maintenance therapy, in relation to the current standard of care consisting of IVIG and SCIG (IgPro20) treatment.
- Cost inputs included drug acquisition (pharmacy) costs, administration costs by site of care, infusion-related complications, systemic side effects, and indirect costs.[2-6]
- Pharmacy costs were based on a payment mix of average sales price (ASP) (73%), wholesale acquisition cost (WAC) (2%), and average wholesale price (AWP) (25%).[7]
- The PATH clinical study of IgPro20 (Hizentra) maintenance was the basis for input on relapse rates at initial assessment (24 weeks) and at 52 weeks for each of its 2 doses – high dose (0.4 g/kg/bodyweight (bw) and low dose (0.2 g/kg/bw).[8,9]
- The ICE clinical study of IVIG maintenance therapy was the basis for input on relapse rates for IVIGs
- The recent ADHERE clinical study was used to obtain relapse rates of efgartigimod.[10,11]

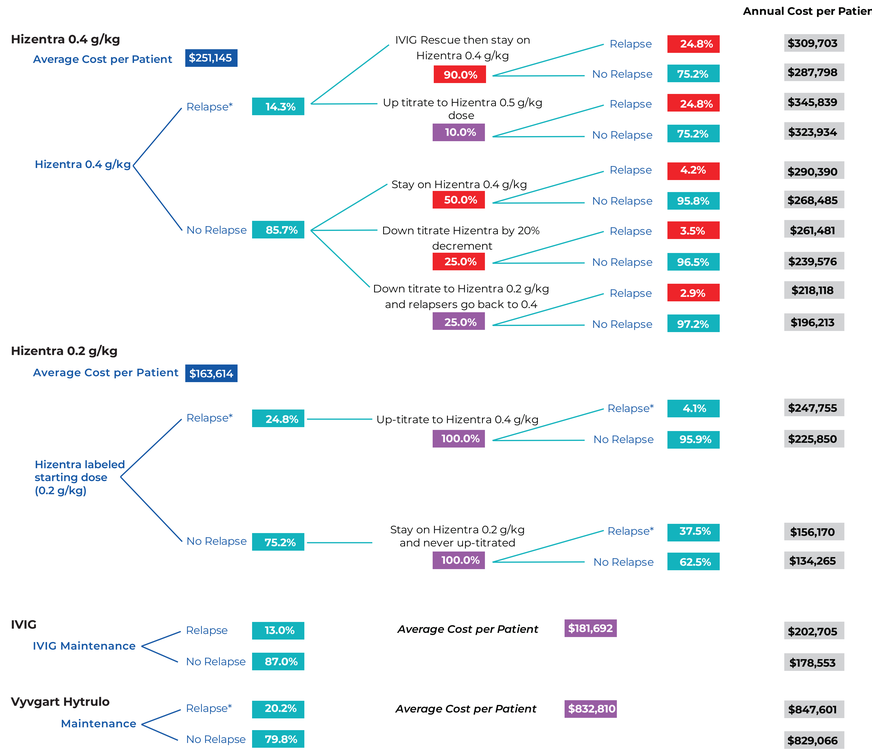
Table 1. Pharmacy costs

	Hizentra	IVIG	Vyvgart Hytrulo
Reimbursed Average Sales Price (ASP)	$12.73 (100 mg)	$48.35 (500 mg)	$16,050.00 (1 g)
Wholesale Acquisition Cost (WAC)	$227.42 (1 g)	$165.94 (1 g)	$16,586.69 (1 g)
Average Wholesale Price (AWP)	$211.12 (1 g)	$154.04 (1 g)	$15,397.45 (1 g)
Average Price per Gram	**$150.24**	**$112.42**	**$15,897.60**

Results

- For a hypothetical 25-million-member health plan, the analysis estimated, based on the prevalence of disease and IG treatment, an expected 708 CIDP patients treated with IG.
- **Figure 1 presents:**
  - Patient flow for each of the treatment options for CIDP maintenance therapy
  - Associated relapse rates based on respective clinical studies and subsequent patient management, as relevant
  - Expected costs for each treatment option

Figure 1. Model structure and cost per patient per year



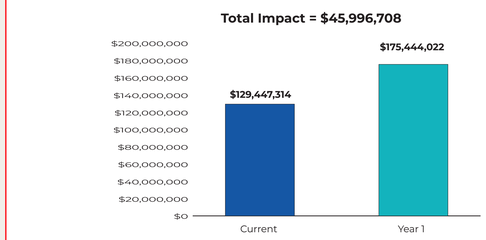
* Rates have been adjusted using a relative risk reduction approach to account for study heterogeneity between the PATH/ICE studies.
Key: IVIG – intravenous immunoglobulin.

- Based on its publicly available US pricing for myasthenia gravis as translated to CIDP dosing, Vyvgart is expected to cost $832,810 for annual cost of CIDP treatment compared to $251,790 for the Hizentra high dose (0.4 g/kg/bw) and $163,929 for the Hizentra low dose (0.2 g/kg/bw).
- Assuming a 10% uptake of efgartigimod alfa in year 1, (drawing patient share proportionally from IVIG and SCIG) yielded a total projected budget impact of $45,996,708, a 35.5% increase.

Table 2. Total cost increase, assuming assuming a 10% uptake of efgartigimod alfa in year 1, drawing patient share proportionally from IVIG and SCIG

	Current	Year 1	Budget Impact	Percentage Change
Drug costs	$106,636,966	$154,714,897	$48,077,931	45.1%
Non-drug costs	$22,791,732	$20,712,281	-$2,079,450	-9.1%
Total costs	$129,447,314	$175,444,022	$45,996,708	35.5%

Figure 2. Budget impact assuming a 10% uptake of efgartigimod alfa in year 1, drawing patient share proportionally from IVIG and SCIG



Key: IVIG – intravenous immunoglobulin; SCIG – subcutaneous immunoglobulin.

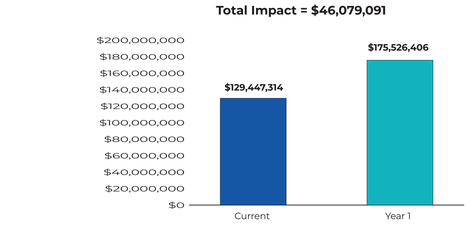
Results *cont.*

- Assuming a 10% uptake of efgartigimod alfa in year 1 (drawing patient share exclusively from IVIG) led to a projected total budget impact of $46,079,091, a 35.6% increase.

Table 3. Total cost increase, assuming a 10% uptake of efgartigimod alfa in year 1 drawing patient share exclusively from IVIG

	Current	Year 1	Budget impact	Percentage change
Drug costs	$106,636,966	$154,938,938	$48,301,972	45.3%
Non-drug costs	$22,791,732	$20,568,851	-$2,222,881	-9.8%
Total costs	$129,447,314	$175,526,406	$46,079,091	35.6%

Figure 3. Budget impact assuming a 10% uptake of efgartigimod alfa in year 1 drawing patient share exclusively from IVIG



Key: IVIG – intravenous immunoglobulin.

Conclusion

- This analysis suggests that efgartigimod alfa is expected to result in substantially increased spending in treatment of CIDP. This conclusion follows from:
  - Substantially higher publicly known price of efgartigimod alfa, as translated via dose adjustment from myasthenia gravis pricing to CIDP pricing.
  - The absence of a documented relapse management approach with efgartigimod alfa, as opposed to known relapse management outcomes documented in the PATH open-label extension study, and incorporating the cost of untreated relapses.

References

1. Bunschoten C, Jacobs BC, Van den Bergh PYK, Cornblath DR, van Doorn PA. Progress in diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy. *Lancet Neurol*. 2019;18(8):784-794.
2. Red Book Online. IBM Micromedex. Copyright IBM Corporation 2023. Accessed November 8, 2023.
3. Centers for Medicare and Medicaid Services (CMS). Effective October 1, 2023 through December 31, 2023 Pricing File. Accessed November 8, 2023. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files
4. Centers for Medicare and Medicaid Services (CMS). Hospital Outpatient Prospective Patient System (OPPS). Accessed November 8, 2023. https://www.cms.gov/license/ama?file=/files/zip/october-2023-opps-addendum-b.zip
5. Slen B. Infused therapies: cost savings benefits through home infusion. *Specialty Pharmacy Times*. 2014;5(1):24-25.
6. Centers for Medicare and Medicaid Services (CMS). Physician Fee Schedule Search. Page last modified: September 6, 2023. Accessed November 8, 2023. https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx
7. AMCP. AMCP Pharmaceutical Payment Methods, 2013 Update. 2013. Accessed November 28, 2022. https://www.amcp.org/guide-pharmaceutical-payment-methods
8. Van Schaik I, Bril V, van Geloven et al. Subcutaneous immunoglobulin for maintenance treatment in chronic inflammatory demyelinating polyneuropathy (PATH): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2018;17:35-46.
9. Van Schaik I, Meilke O, Bril V, et al. Long-term safety and efficacy of subcutaneous immunoglobulin IgPro 20 in CIDP. *Neurol Neuroimmunol Neuroinflamm*. 2019;6(5):e590.
10. Hughes R, Donofrio P, Bril V, et al. Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. *Lancet Neurol*. 2008;7: 136-144.
11. argenx press release. argenx reports positive topline data from ADHERE study of Vyvgart Hytrulo in patients with chronic inflammatory demyelinating polyneuropathy. July 17, 2023. https://www.us.argenx.com/sites/default/files/media-documents/Press-Release_ARGX_ADHERE_Data_Release.pdf

Disclosures

- Mallick R and Hubsch A are employees of CSL Behring; Carlton R and van Stiphout are employees of Cencora; Lahue B is an employee of Alkemi
- This study was funded by CSL Behring

Presented at ISPOR 2024 | May 5-8, 2024 | Atlanta, GA