Triamcinolone Acetonide Injectable Suspension, for Suprachoroidal Use, for the Treatment of Macular Edema Associated with Uveitis in the United States: A Budget Impact Analysis

Subrata Bhattacharyya[1], Seenu M Hariprasad[2], Thomas A Albini[3], Denny John[1], Sekhar K Dutta[1], Benjamin G Cohen[4], Ankur A Dashputre[5], David Harrison[5], George Joseph[5]

[1] PharmaQuant, Kolkata, India, [2] The University of Chicago Medicine & Biological Sciences, Chicago, USA, [3] Bascom Palmer Eye Institute, University of Miami, Florida, USA, [4] Monument Analytics, Baltimore, USA, [5] Bausch Health, New Jersey, USA

Background

- Non-infectious uveitis (NIU) is a serious, sight-threatening intraocular condition characterized by inflammation of the uvea (iris, ciliary body, and choroid) with a prevalence rate of 121 cases per 100,000 US adults (2016).[1]
- Macular edema (ME), characterized by abnormal thickening of the macula, is one of the most common complications of NIU.[2,3] Based on a claims-based analysis, the prevalence of ME associated with NIU (ME-NIU) in the US is estimated at 9.1%.[4]
- In October 2021, the US Food and Drug Administration (FDA) approved the suprachoroidal injection of a unique formulation of triamcinolone acetonide, a synthetic corticosteroid as the first treatment indicated for ME associated with uveitis (specifically NIU), based on the clinical efficacy and safety profile demonstrated in the Phase III PEACHTREE study.[5]
- Understanding the budget impact of this therapy for ME-NIU is critical for payers when making reimbursement decisions for this new agent. The objective of this study was to assess the budget impact of triamcinolone acetonide injectable suspension, for suprachoroidal use, for ME-NIU in the US from the Commercial and Medicare perspectives.

Methods

- A budget impact model (BIM) using an incidence-based approach comparing scenarios with and without triamcinolone acetonide, for suprachoroidal use, was constructed using Microsoft® Excel.
- Model Overview **(Figure 1)**:
  - *Population:* Adult patients (≥18 years) with ME-NIU
  - *Payer perspective and eligible population size:* US Commercial (18-64 years) and Medicare (≥18 years) plans, each with a hypothetical 1-million-member population
  - *Time Horizon:* 5 years
  - *Treatment scenarios:* With triamcinolone acetonide injectable suspension for suprachoroidal use vs without triamcinolone acetonide injectable suspension for suprachoroidal use
- Model inputs:
  - *Epidemiology:* Annual incidence (over 5-year study horizon) of patients with ME-NIU eligible for triamcinolone acetonide injectable suspension, for suprachoroidal use, was estimated based on US census data, published literature, and claims-based US prevalence of NIU and ME **(Table 1)**.[4,6,7]
  - *Market share* assumptions are based on the expected uptake rate of triamcinolone acetonide injectable suspension for suprachoroidal use.
  - *Efficacy* of triamcinolone acetonide injectable suspension, for suprachoroidal use, is based on data from the Phase III PEACHTREE study **(Table 2)**. It was conservatively assumed that there would be no further vision improvement beyond 24 weeks and that no additional injections would be required in the first year.
  - Two injections per ME-affected eye are assumed in the BIM based on the Phase III PEACHTREE study.[8] In subsequent years, in the absence of retreatment data, it was assumed that 70% of patients would require one injection and 30% of patients would require two injections per ME-affected eye, for an average of 1.3 injections per eye to be able to retain the vision improvement gained in the first 24 weeks of treatment.
  - Cost inputs:
    - *Wholesale Acquisition Cost* of triamcinolone acetonide injectable suspension for suprachoroidal use: $1,650
    - *Drug administration* cost: $200 (assumption)
    - *Healthcare utilization* costs including eye-related inpatient, outpatient, emergency department (ED) visit costs, and non-eye related medical costs (including inpatient, outpatient, ED visits); pharmacy costs (eye and non-eye related) by vision loss status.[4]
- Model outputs: *Plan-level* and *per member per month* (PMPM) costs in 2020 USD
- Sensitivity/scenario analyses: *One-way sensitivity* and *scenario analyses* were performed as per the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) best practices guidelines.[9] All scenarios followed a model time horizon of 5 years, except the one where the results were tested for a model time horizon of 3 years.
- The model was developed in accordance with recommendations from the ISPOR Task Force Report: Budget Impact Analysis.[9]

BAUSCH + LOMB

Figure 1: Schematic presentation of budget impact model flow

LSI – local steroid injection; ME – macular edema; NIU – non-infectious uveitis; PMPM – per member per month

Table 1: Epidemiological inputs in the model

Model parameters (Hypothetical cohort N=1,000,000)	Commercial (18-64 years)	Medicare (≥18 years)
Adult population[6]	77.8% [N=777,700]	99.2% [N=992,000]
Proportion of patients with uveitis[7]	0.1% [N=851]	0.2% [N=2,184]
Proportion of patients with non-infectious uveitis (NIU)[7]	93.7% [N=797]	86.2% [N=1,882]
Proportion of NIU patients with macular edema (ME) associated with NIU at any time[4]	9.1% [N=72]	14.5% [N=273]
Proportion of patients with an ME diagnosis per year (re-treatment)[4]	47.8% [N=35]	50.8% [N=138]
Proportion of patients with an ME diagnosis who received an LSI annually[4]	23.3% [N=8]	23.4% [N=32]
Proportion of patients who have bilateral ME associated with NIU requiring LSI[4]	50.1% [no. of patients = 8; no. of eyes = 12]	40.4% [no. of patients = 32; no. of eyes = 45]

LSI - local steroid injection; ME – macular edema; NIU - non-infectious uveitis

Table 2: Distribution of vision loss severity by 24 weeks in the PEACHTREE study[10]

	Triamcinolone acetonide injectable suspension, for suprachoroidal use	Sham injection	Source
No vision loss (BCVA ≥ 70)[a]	81.3%	67.2%	Data on file, PEACHTREE study[10]
Moderate vision loss (40 ≤ BCVA <70)[b]	16.7%	28.1%	
Severe vision loss (20 < BCVA < 40)[c]	2.1%	4.7%	
Blindness (BCVA: ≤ 20)[d]	0.0%	0.0%	

BCVA – best corrected visual acuity. Notes: BCVA letter score from the best seeing eye is considered for the analysis and assumption of the BCVA score were based on clinical expert opinion.
a: No vision loss (BCVA ≥ 70); b: Moderate vision loss (40 ≤ BCVA <70); c: Severe vision loss (20 < BCVA < 40); d: Blindness (BCVA: ≤ 20)

Results

Figure 2: Total plan-level budget impact per one million members by payer type

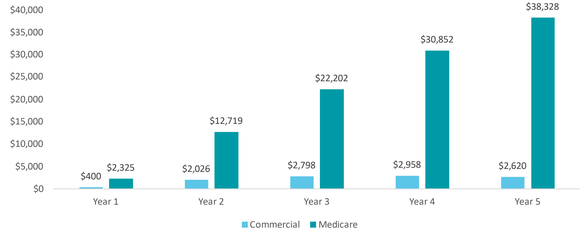
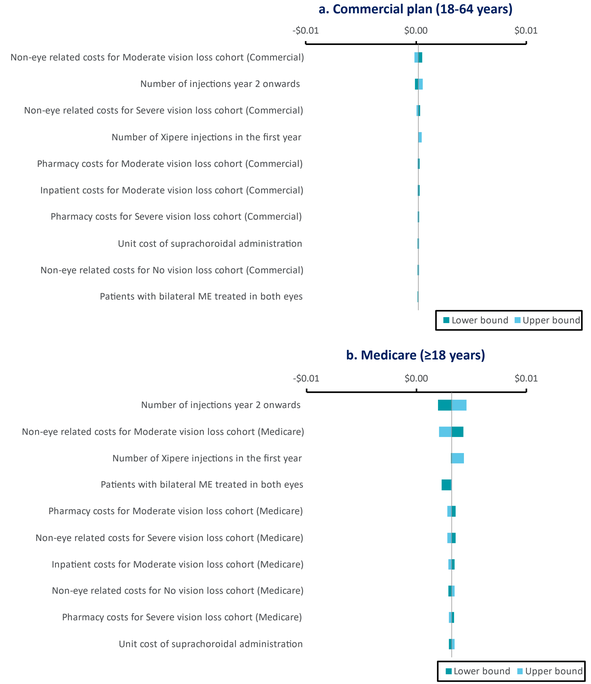


Figure 3: PMPM budget impact per one million plan members



ME – macular edema; NIU – non-infectious uveitis; PMPM – per member per month

- For a hypothetical population of one million Commercial plan members, the total plan level budget impact of triamcinolone acetonide injectable suspension, for suprachoroidal use, for the treatment of ME-NIU was estimated to be $2,600 at year 5 **(Figure 2)**.
  - The PMPM budget impact was estimated to be less than a cent from Year 1 through Year 5.
- For a hypothetical cohort of one million Medicare plan members, the total plan-level budget impact of triamcinolone acetonide injectable suspension, for suprachoroidal use, for the treatment of ME-NIU was estimated to be $38,300 at year 5 **(Figure 2)**.
  - The PMPM budget impact was estimated to be less than a cent from Year 1 through Year 5.
- Deterministic one-way sensitivity analysis suggested that the plan level budget impact remained below $10,000 per million Commercial plan members and below $60,000 per million Medicare plan members, and the PMPM costs remained less than a cent for both the Commercial and Medicare populations **(Figure 3a and Figure 3b)**. Scenario analysis suggested that triamcinolone acetonide injectable suspension, for suprachoroidal use, had little to no impact on the payers' budget **(Table 3)**.

Table 3: Scenario analysis

Scenario description	Plan-level impact	PMPM impact
Commercial – model horizon set to 3 years	$2,800	$0.0002
Commercial – number of injections per eye set to 2 in the subsequent years	$14,000	$0.0012
Medicare – model horizon set to 3 years	$22,200	$0.0019
Medicare – number of injections per eye set to 2 in the subsequent years	$81,100	$0.0068

PMPM – per member per month

Limitations

Given the paucity of FDA-approved therapy for the treatment of ME-NIU, many treatments that are approved for NIU are used off-label to treat ME-NIU; however, they are not always coded for ME-NIU in the claims database. This underreporting may potentially lead to an underestimate of the incidence and costs associated with ME-NIU in the model.

Conclusions

- The introduction of triamcinolone acetonide injectable suspension, for suprachoroidal use, for the treatment of ME-NIU in the US is cost-neutral and could lead to lower inpatient, outpatient, ED, non-eye related treatment, and pharmacy costs, benefitting the US healthcare system.
- Increased costs of treatment with triamcinolone acetonide injectable suspension, for suprachoroidal use, are likely to be offset by reduced healthcare resource utilization costs associated with the use of this agent.

References

1. Yeh S. The burden of noninfectious uveitis of the posterior segment: A Review. Retina Today [Internet]. 2016; (July/August2016).
2. Massa H. Macular edema associated with non-infectious uveitis: pathophysiology, etiology, prevalence, impact and management challenges. Clin Ophthalmol. 2019;13:1761-77.
3. Cho HY. A three-year follow-up of intravitreal triamcinolone acetonide injection and macular laser photocoagulation for diffuse diabetic macular edema. Korean J Ophthalmol. 2012;26(5):362-8.
4. Hariprasad SM. Healthcare costs among patients with macular oedema associated with non-infectious uveitis: a US commercial payer's perspective. BMJ Open Ophthalmol. 2021;6(1):e000896.
5. Food and Drug Administration (FDA). XIPERE™ (triamcinolone acetonide injectable suspension), for suprachoroidal use. 2021.
6. United States Census Bureau. US Population; S0101 - 2019: ACS 1-Year Estimates Subject Tables 2021.
7. Thorne JE. Direct and indirect resource use, healthcare costs and work force absence in patients with non-infectious intermediate, posterior or panuveitis. Acta Ophthalmologica. 2016;94(5):e331-e9.
8. Yeh S. Efficacy and Safety of Suprachoroidal CLS-TA for Macular Edema Secondary to Noninfectious Uveitis: Phase 3 Randomized Trial. Ophthalmology. 2020;127(7):948-55.
9. Sullivan SD. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health. 2014;17(1):5-14.
10. Data on file, PEACHTREE study [ClinicalTrials.gov registration - NCT02595398]; Bausch Health LLC.

Disclosures

- This study was funded by **Bausch Health US, LLC**
- The study sponsor was involved in several aspects of the research, including study design, the interpretation of the data, and the production of the poster.