BUDGET IMPACT MODEL OF NEW ORAL TREATMENTS FOR UNCOMPLICATED UROGENITAL GONORRHEA

Authors: Shellie Keast, PharmD, PhD[1]; James Chamberlain, PharmD, MS[1]; Wenyi Qiu, MS[1]; Jennifer Hendricks, Pharm.D., APh, BCACP, CDCES, FCPhA[1]
Affiliations: 1. MedImpact Healthcare Systems, San Diego, CA, USA

INTRODUCTION

- The Centers for Disease Control and Prevention (CDC) estimates approximately 1.6 million new cases of gonococcal infections occur in the U.S. each year.[1]
- Of those, approximately 34% are diagnosed, with only 70% of identified cases being treated, as many gonococcal infections may remain asymptomatic until complications occur.[1-3]
- Current standard of care for uncomplicated urogenital gonorrhea is a single dose of intramuscular ceftriaxone 500mg.[1]
- Studies have shown that azithromycin either alone or with ceftriaxone is used in approximately 75% of cases, despite wide-spread antimicrobial resistance to these two agents.[4]
- Two new treatment options were approved by the Food and Drug Administration (FDA) in December 2025: gepotidacin, a triazaacenaphthylene, and zoliflodacin, a spiropyrimidinetrione.

OBJECTIVE

To investigate the future financial impact using a budget impact model (BIM) for the treatment of uncomplicated urogenital gonorrhea in a hypothetical 1-million-member commercial health plan.

METHODOLOGY

Study Design

- A budget impact model was developed to estimate the financial effects of pharmacy benefit plan uptake of both gepotidacin and zoliflodacin in the targeted population.
- A hypothetical commercial health plan was modeled based on 1 million member lives with a one-year time horizon.
- The model was constructed in accordance with industry standards and best practice guidelines.[5,6]

Population

- Total incidence of uncomplicated urogenital gonorrhea in the U.S. was estimated to be ~1.6 million cases based on CDC reporting.[1]
- The percentage of the population diagnosed or reported was approximately 38% with an additional 70% treated.[3]
- The U.S. total commercial population was estimated to be 184 million.[7]

Model Inputs

- Because treatment is a single occurrence, no adjustments were made for adherence.
- Current standard of care prescribing patterns are shown in Table 2.[4]

Costs

- Medication costs were modeled using MedImpact ingredient cost for current therapies, published pricing (AWP, HCPCS, etc.), or estimated future pricing.
- Administrative costs for injections were included, but no physician office visit fees were considered as it was assumed office visits for diagnostic purposes would continue.

Sensitivity and Scenario Analyses

- One-way sensitivity analyses were conducted on the model inputs and varied by +/- 20%.

METHODOLOGY, CONT.

Table 1. Breakdown of Uncomplicated Genitourinary Gonorrhea Incidence in the Populations of Interest

U.S. Population		Commercial Population	
U.S. Population	342,423,075	Commercial Population	184,223,614
U.S. New Gonorrhea Cases Per Year	1,568,000	Commercial New Gonorrhea Cases Per Year	292,354
Percent of U.S. Population with Newly Diagnosed Gonorrhea	0.46%	Percent of Commercial Population with Newly Diagnosed Gonorrhea	0.16%

Figure 1: Patient Identification Flowchart for the Hypothetical Commercial Plan

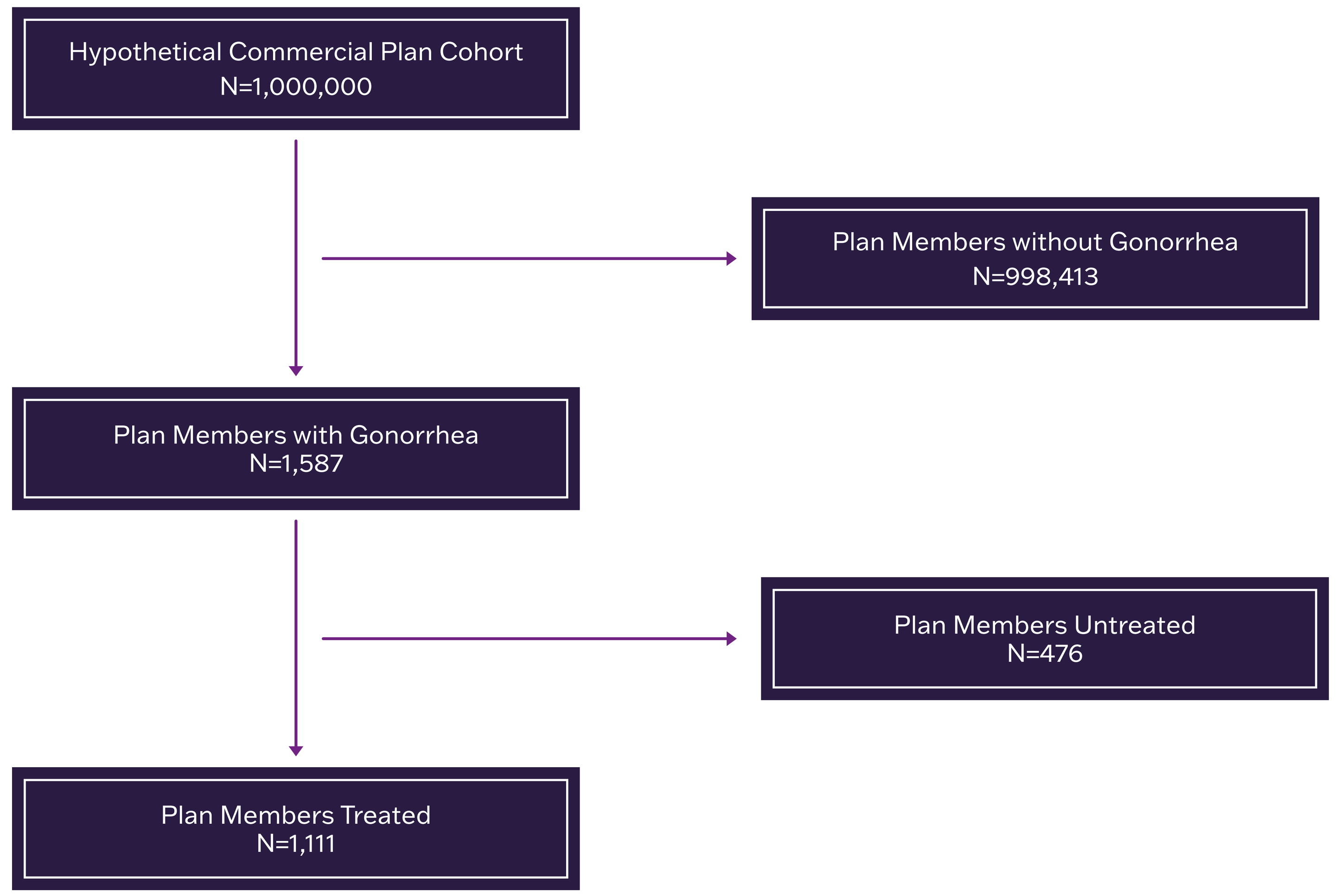


Table 2. Current Prescribing Treatment Patterns

Treatment	Percent Prescribed
Ceftriaxone with Azithromycin	25.4%
Ceftriaxone Only	13.2%
Azithromycin Only	59.5%

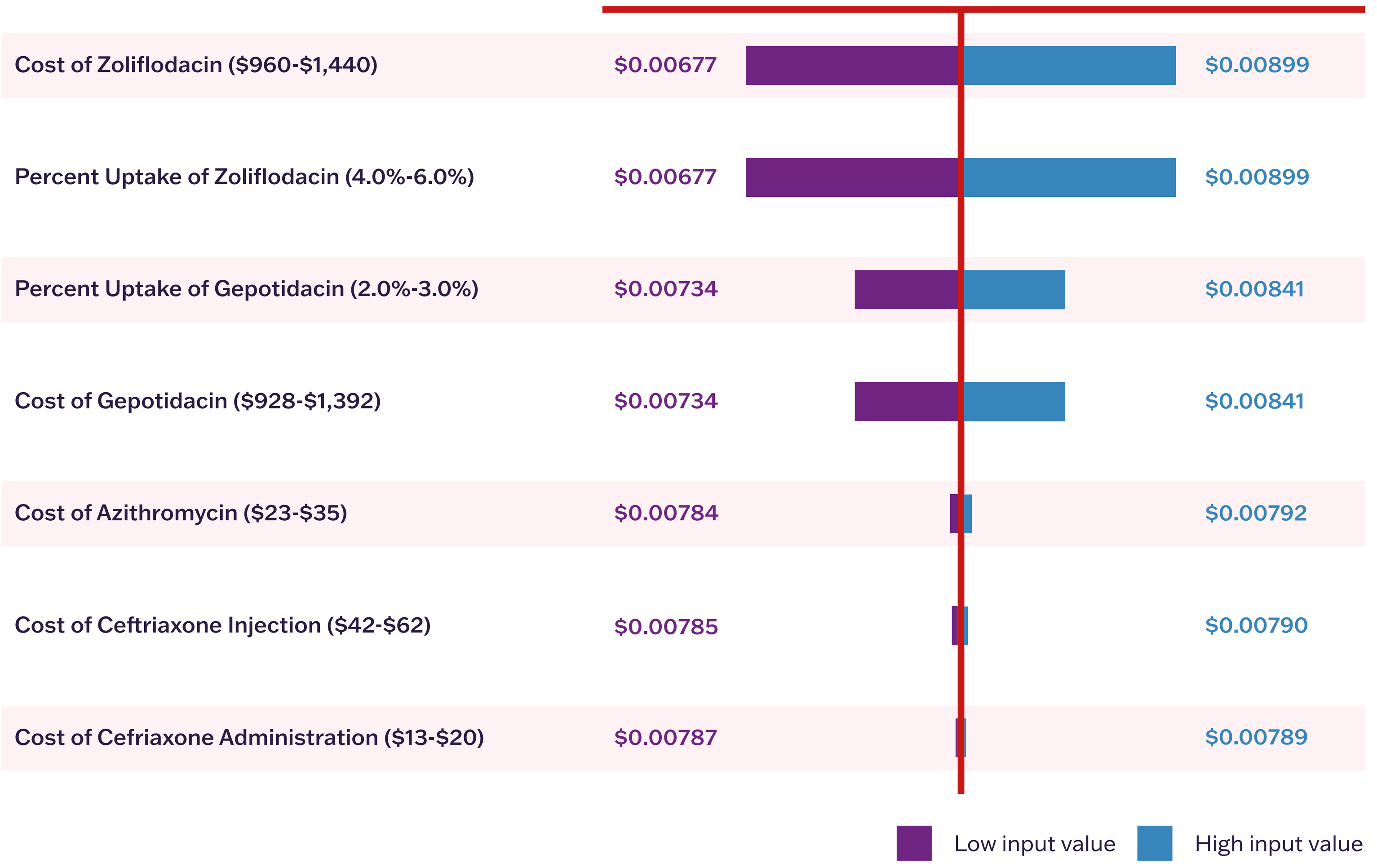
RESULTS

Table 3: Incremental Cost Results

Outcome	Cost
Incremental Aggregate Cost	$151,472
Incremental PPPY Cost	$136.35
Incremental PPPM Cost	$11.00
Incremental PMPM Cost	$0.008

PPPY: Per-patient per-year; PPPM: Per-patient per-month; PMPM: Per-member per-month

Figure 2: Budget Impact PMPM Sensitivity Analysis



DISCUSSION

- In the commercial plan, an estimated 1,111 patients were treated each year.
- The projected budget impact was a $151,472 increase in pharmacy plan spend ($0.008 PMPM).
- Sensitivity analysis indicated the results were most sensitive to changes in price and uptake for the new products, with zoliflodacin changes causing the largest fluctuations in PMPM.

Limitations

- The model did not account for any offsets in medical costs other than the cost of ceftriaxone administration.
- Medical cost offsets are expected to be minimal based on the assumption that all patients would still incur the same medical costs associated with diagnosis and prescribing.
- This review was from the payer perspective and did not include any consideration for patient out-of-pocket expenses.
- Costs for different payers and final costs for new therapies may change the results of the analyses.
- The population modeled is hypothetical and may not reflect prevalence in an actual population, generalizability may be limited.
- Geographic variances may vary and can affect the prevalence of gonorrhea in a given plan.

CONCLUSION

While early uptake of new oral antibiotic therapies may be limited, the price per treatment difference between ceftriaxone and/or azithromycin and the new therapies, along with the shift to the pharmacy benefit, will result in an increase in the pharmacy PMPM for plans. Plans will experience the impact as physicians begin to adopt these newer therapies in place of injectable ceftriaxone or resistance-associated azithromycin-only prescribing.

REFERENCES

1. Gonococcal Infections Among Adolescents and Adults - STI Treatment Guidelines. www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm#print.
2. Sexually Transmitted Infections Surveillance, 2024 (Provisional). STI Statistics. Published September 24, 2025. https://www.cdc.gov/sti-statistics/annual/index.html
3. Are Patients Not Following Through with STI Treatment? American Sexual Health Association. Published May 9, 2025. https://www.ashasexualhealth.org/are-patients-not-following-through-with-sti-treatment/
4. Hao S, Tao G, Rochliin I, Phillips RL, Rehkopf DH, Kamdar N. Treatment of chlamydia and gonorrhea in primary care and its patient-level variation: an American family cohort study. Ann Fam Med. 2025;23:136-144. https://doi.org/10.1370/afm.240164
5. Sullivan SD, Mauskopf JA, Augustovski F, et al. 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. doi:10.1016/j.jval.2013.08.2291
6. Academy of Managed Care Pharmacy. The AMCP Format for Formulary Submissions (version 5.0). Academy of Managed Care Pharmacy. J Manag Care Spec Pharm. 2024;30(4-b):supplement.
7. Health insurance coverage in the United States: 2024. Published September 9, 2025. Accessed October 2, 2025. https://www.census.gov/library/publications/2025/demo/p60-288.html

SCAN HERE