

Private payer-negotiated prices for FDA-approved biologic treatments for allergic diseases

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INTRODUCTION

Novel biologic agents have recently emerged as treatments for allergic disease. At present, five monoclonal antibodies (mAbs) have received US Food and Drug Administration (FDA) approval for treatment of allergic diseases, such as asthma and chronic sinusitis with nasal polyposis (CRSwNP) (Supplement).¹ However, there are concerns that high prices may limit the cost-effectiveness of mAbs.

The cost of mAbs is a function of manufacturer selling prices and subsequent price markups by supply chain intermediaries (e.g., wholesalers) and provider organizations (i.e., physician offices or hospital outpatient departments) that ultimately administer the drugs.² While high manufacturer sales prices for mAbs have received much attention,³ less is known about the extent to which provider organizations may inflate mAb prices. Provider organizations and insurance companies have historically considered negotiated prices for drugs to be proprietary information. Recent analysis of deidentified commercial insurer claims suggests that prices for biologics are approximately 70% greater at hospitals than at physician offices.⁴

On January 1, 2021, the Centers of Medicare and Medicaid Services (CMS) implemented the Hospital Price Transparency final rule, which required hospitals to publish payer-negotiated prices for all items and services online.⁵ We analyzed newly available price data disclosed in compliance with this law to investigate the extent of hospital price markup for mAbs and of price variation among hospitals and within hospitals between payers.

METHODS

We performed a cross-sectional analysis of payer-negotiated prices for mAbs at the top 50 hospitals ranked by US News & World Report (USNWR) in Pulmonology in 2020–2021. USNWR does not include the field of allergy/immunology in specialty rankings. We restricted analysis to these hospitals anticipating that they would possess the organizational resources to comply with the price transparency rule. Our analysis included four out of the five currently FDA-approved mAbs for treatment of allergic diseases: omalizumab, mepolizumab, reslizumab, and benralizumab ([Supplement](#)). We excluded dupilumab because it is not associated with a unique Health Common Procedures Coding System code.

Using previously described methods,⁶ we identified and reviewed each hospital website for publicly available price transparency files ([Supplement](#)) to extract private payer-negotiated rates for included mAbs. We used descriptive statistics to characterize hospital disclosure rates and prices for each mAb.

We then determined hospital price markup by calculating the percent increase of the median of median hospital payer-negotiated prices relative to manufacturer average sales price (ASP), which we imputed from the July 2021 Medicare ASP Drug Pricing file.⁷ We expressed price markup as a relative percent increase in excess of ASP—which is net of all manufacturer rebates, discounts, and price concessions—to facilitate comparison between mAbs.

We next assessed price variation both across hospitals and within hospitals between payers.⁶ To compare price variation across hospitals, we first normalized the median payer-negotiated price for each drug at each hospital to the hospital-specific Medicare geographic practice cost index (GPCI). We subsequently calculated the ratio of the 90th-to-10th percentile GPCI-normalized median prices for each drug (“across-center ratio”). To compare prices within each hospital, we calculated the ratio of the 90th-to-10th percentile payer-negotiated price (“within-center ratio”).

All available prices were current as of August 24, 2021. Statistical analysis was performed using R, version 4.0.4. This study did not require institutional review board approval or exemption because all data were nonclinical and publicly available.

RESULTS

Among the top 50 hospitals ranked by USNWR in Pulmonology in 2020–2021, 20 (40%) disclosed payer-negotiated prices for at least one mAb approved for the treatment of allergic disease. Hospital price disclosure rates ranged between 22% ($n = 11$; both reslizumab and benralizumab) and 38% ($n = 19$; omalizumab) (Table 1). Payer-negotiated prices were consistently higher than ASPs for the drugs in our sample (Figure 1), with median price markups ranging from +101.4% (omalizumab) to +149.4% (reslizumab) in excess of ASP.

TABLE 1. Private payer-negotiated prices of monoclonal antibodies for treatment of allergic

diseases

Biologic (dose)	HCPCS Code	N Centers (%)	Median payer- negotiated price (IQR) (\$) ^a	Mean payer- negotiated price (SD) (\$) ^a	Minimum median payer- negotiated price (\$) ^a	Maximum median payer- negotiated price (\$) ^a	Across- center price ratio ^b	N w c p r (I
Omalizumab (150 mg/ml)	J2357	19 (38%)	2160 [1465–3101]	2337 [896]	1077	3802	3	1 [
Mepolizumab (100 mg/ml)	J2182	14 (28%)	5732 [4435–7468]	5832 [1878]	2929	8857	2.4	1 [
Reslizumab (100 mg/10 ml)	J2786	11 (22%)	2342 [1476–2755]	2176 [820]	1013	3355	3.4	1 [
Benralizumab (30 mg/ml)	J0517	11 (22%)	10,636 [8648–12,487]	10,092 [2692]	5604	13,428	2.1	1 [

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; IQR, interquartile range; SD, standard deviation.

^a Median, mean, minimum, and maximum prices calculated based on the median payer-negotiated prices at each included hospital.

^b Across-center ratio calculated as ratio of the 90th and 10th percentile hospital-specific median payer-negotiated prices (normalized to geographic practice cost index [GPCI]).

^c Within-center ratio calculated as the median of the 90th-to-10th percentile ratios of payer-negotiated prices at each hospital.

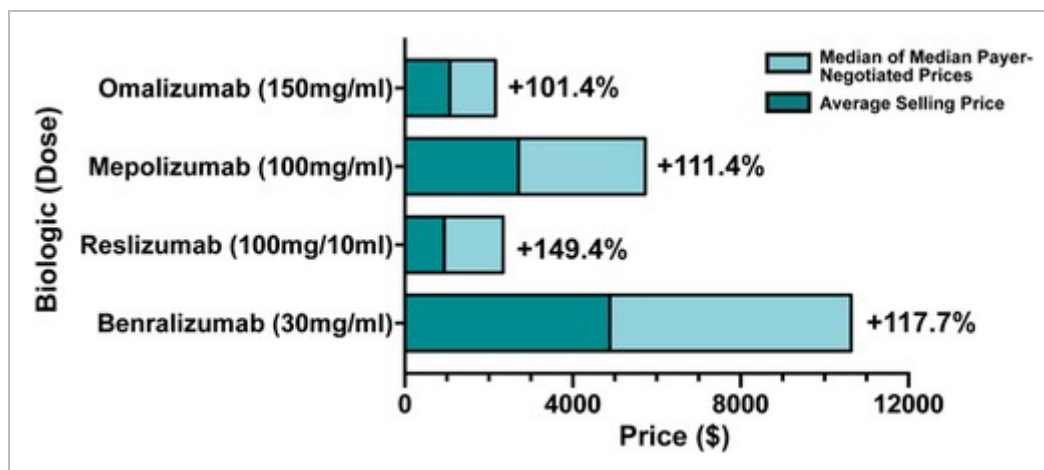


FIGURE 1[Open in figure viewer](#) | [↓ PowerPoint](#)

Hospital markup on Food and Drug Administration (FDA)-approved monoclonal antibodies for the treatment of allergic diseases. Median based on the median payer-negotiated prices at each included hospital. Markup calculated as excess relative to manufacturer average sales price

mAb prices varied widely across hospitals (Table 1). Across-center ratios ranged between 2.1 (benralizumab; raw median price range: \$5604–\$13,428) and 3.4 (reslizumab; raw median price range \$1013–\$3355). Negotiated prices also varied between payers at each hospital; median within-center ratios were 1.5 for reslizumab and 1.7 for omalizumab, mepolizumab, and benralizumab.

DISCUSSION

A minority of the top 50 hospitals ranked by USNWR in pulmonology publicly disclosed payer-negotiated prices for mAbs as required by law. Negotiated prices varied widely among disclosing hospitals and were typically more than double the manufacturer ASP. Within hospitals, negotiated prices varied substantially between payers. The considerable extent of price variation and markup likely reflects relative differences in market power between hospitals and private insurers.

These findings have important implications for practice and research. Given that mAbs are often dosed every 4 weeks, patients may incur significant financial burden over the course of treatment, particularly patients with high deductibles or coinsurance rates. Physicians should counsel patients on expected costs before initiating treatment⁸ and consider options to reduce the financial burden of treatment, such as permitting at-home administration by patients or caregivers when appropriate. Cost-effectiveness research based on manufacturer ASPs may overestimate the cost-effectiveness of mAbs given substantial downstream markup on the prices ultimately borne by patients and payers. For example, recent analysis of asthma treatment with omalizumab by the Institute for Clinical and Economic Review used a manufacturer net price of \$28,900 per year (total amount: 36 150-mg vials) to estimate a cost-effectiveness ratio of \$325,000 per quality-adjusted life year,⁹ but the median payer-negotiated price per year of omalizumab for hospitals in our study is approximately \$78,000.

Given that available analyses may also substantially overestimate the cost-effectiveness of mAbs for CRSwNP,¹⁰ physicians should consider reserving therapy for patients with truly recalcitrant disease that have failed standard of care treatment, including thorough endoscopic sinus surgery. For the select patients that may be appropriately treated with mAbs, physicians should carefully choose among available therapies with the understanding that widely different prices may exist. Future comparative and cost-effectiveness research may help guide these clinically and financially important decisions.

Our study has limitations. Our findings may not be generalizable to other hospitals, physician offices, or other types of drugs. Additionally, our results may not be applicable to patients seeking to comparison shop because we did not estimate out-of-pocket costs. Finally, we may underestimate the extent of markup as hospitals in our cohort likely have the market power to purchase drugs at a cost below the ASP or through the 340B drug pricing program.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

Supporting Information

Filename	Description
alr22922-sup-0001-SuppMat.docx 21.6 KB	Supplementary information

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Supplemental Methods

Additional Information on Price Extraction Methods

For each hospital with an available price transparency file, we extracted private payer-negotiated rates for the four mAbs in our sample using Healthcare Common Procedure Coding System (HCPCS) codes. We extracted prices for the most commonly disclosed dosage for each mAb. If prices for this dosage were not available, we converted the disclosed dosage to the most commonly listed dosage amount (e.g., 150 mg/mL for omalizumab; **Table**). Prices listed for government payers (e.g., Medicare, Medicare Advantage, Medicaid, veterans plans) and international insurance plans were excluded as prices set by these plans are negotiated differently. Only hospitals that disclosed at least five payer-negotiated prices for each drug were included to minimize variation due to outliers.

Determining Hospital Price Markup

We determined hospital price markup by calculating the percent increase of the median of median hospital payer-negotiated prices relative to manufacturer average sales price (ASP). ASP equals the quotient of Medicare payment amounts listed in the July 2021 Medicare ASP Drug Pricing file¹ and 106%.²

Supplemental Table. FDA-Approved Biologic Treatments for Allergic Diseases

Drug	FDA Approval Year¹	Indications¹	Dosing Administration¹
Omalizumab	2003	For adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.	75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg).
Omalizumab	2014	Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment	150 or 300 mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight.
Omalizumab	2018	Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.	75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg).
Omalizumab	2020	Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.	75 to 600 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg).
Mepolizumab	2015	Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.	Severe asthma in patients aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks
Mepolizumab	2017	The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).	300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks
Mepolizumab	2019	Add-on maintenance treatment of patients with severe asthma, and with an eosinophilic phenotype to include patients aged 6 to 11 years.	Severe asthma in patients aged 6 to 11 years: 40 mg administered subcutaneously once every 4 weeks.

Mepolizumab	2020	The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non hematologic secondary cause.	300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks
Mepolizumab	2021	Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).	100 mg administered subcutaneously once every 4 weeks.
Reslizumab	2016	For add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype	Recommended dosage regimen is 3 mg/kg once every 4 weeks by intravenous infusion over 20-50 minutes.
Benralizumab	2017	For the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype	Recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.
Dupilumab	2017	Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	600 mg (two 300 mg injections in different injection sites), followed by 300 mg given every other week.
Dupilumab	2018	Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma	An initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week; OR An initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week or for patients requiring concomitant oral corticosteroids; OR With comorbid moderate-to-severe atopic dermatitis for which DUPIXENT is indicated, start with an initial dose of 600 mg followed by 300 mg given every other week
Dupilumab	2019	Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps	300 mg given every other week

¹Source: Drugs@FDA Database (<https://www.accessdata.fda.gov/scripts/cder/daf/>) as of September 19th, 2021

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