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Drug costs of Medicaid-covered therapies for pemphigus vulgaris treatment

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Abstract

Pemphigus vulgaris is the most common form of pemphigus affecting an estimated 30,000-40,000 people in the United States. Costs of systemic and immunoglobulin therapies for pemphigus vulgaris have remained persistently high. Herein, we address the current costs and changes in costs of immunosuppressive treatments, anti-inflammatory treatments, and immunoglobulin treatments covered by Medicaid for pemphigus vulgaris from 2013-2020.

Keywords: anti-inflammatory, immunoglobulin, immunosuppressive, pemphigus vulgaris

Introduction

Pemphigus vulgaris (PV) is the most common form of pemphigus affecting an estimated 30,000-40,000 people in the United States [1]. Medication costs for PV have been persistently high with annual pharmacy costs averaging \$3558 (SD=8858) per patient in 2018 [2]. Therapeutic management requires specialist expertise and at times, conventional therapy is inadequate in inducing clinical remission.

Conventional corticosteroids continue to be central to PV treatment, but substantial side effects limit long-term administration and a transition to safer long-term therapy is necessary. Immunosuppressive agents like cyclosporine and cyclophosphamide as well as anti-inflammatory agents like tetracycline derivatives and dapsone have proven to be

efficacious in PV treatment. Most recently, infused immunoglobulin-based therapies with targeted rituximab and high-dose intravenous immunoglobulins (IVIg) have been deployed [3]. Herein, we analyze the trends in costs of immunosuppressive, anti-inflammatory, and immunoglobulin therapies available to PV patients.

Discussion

The costs of commonly prescribed systemic medications for treatment of PV were acquired from the National Average Drug Acquisition Cost (NADAC) dataset from December 2013 to February 2020 [4]. The costs of systemic medications were calculated using dosage published in PV treatment guidelines [5], based on a 70kg adult treated for six months.

The costs of commonly used immunoglobulin treatments are not included in the NADAC dataset and instead were extracted from the Magellan Medical Pharmacy Trend Reports from 2013-2019. Rituximab analysis was based on cost of treatment of rheumatoid arthritis (RA), as the approved initiation dosages for PV and RA treatment are identical. The six-month treatment average was calculated for IVIg by averaging prices for all brands covered by Medicaid (Carimune, Flebogamma, Gammagard Liquid, Gamaplex, Gamunex-C/Gammaked, Octagam, Privigen) in the same year [6].

The average cost of systemic immunosuppressants have fluctuated from 2013-2020 (**Figure 1**). Cyclosporine-unmodified (+109.10%) and cyclophosphamide (+27.80%) have significantly increased in cost while methotrexate (-74.64%),

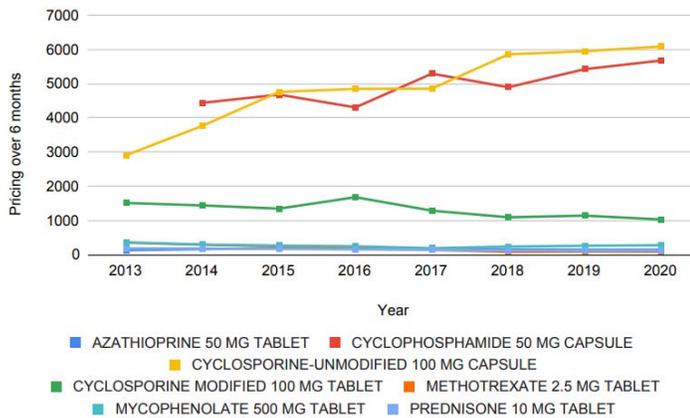


Figure 1. Cost of six months of treatment with systemic immunosuppressive treatment between December 2013 and February 2020. Doses were based on international guidelines for pemphigus vulgaris treatment: azathioprine 2mg/kg/day, cyclophosphamide 2mg/kg/day, methotrexate 15mg/week, mycophenolate 2gm/day, prednisone 1mg/kg/day [5].

prednisone (-34.43%) and cyclosporine-modified (-31.95%) have decreased in price (Table 1). Alternatively, the cost of azathioprine (+8.33%) has remained relatively constant over this period. As of February 2020, cyclosporine-unmodified is the most expensive immunosuppressive costing \$6087 for a 6-month treatment, whereas methotrexate is the least expensive steroid sparing immunosuppressive costing \$89 for a 6-month treatment (Figure 1).

The average cost of anti-inflammatory treatments exhibited bidirectional fluctuations over the past seven years (Figure 2). Doxycycline hyclate (\$385) is the most expensive anti-inflammatory in this category and is 1.4 times more expensive than dapsone (\$268). Although doxycycline hyclate (-94.37%) has declined substantially in price, minocycline (+70.45%) experienced a considerable price increase.

Immunoglobulin therapy is becoming increasingly popular for PV treatment. Rituximab (\$9288) gained FDA approval for PV treatment in June 2018 [7], but data has yet to be published on effects of this approval on treatment cost [6]. Additionally, IVIG treatments (\$14453) have proven efficacious in PV treatment, but to date, Medicaid covers only select IVIG manufacturers and its costs are greater than other therapies reviewed [6]. Immunoabsorption and plasmapheresis are additional therapies shown

to be effective in treating PV but are not covered by Medicaid (Figure 2, Table 1), [3].

Prescribers should be aware of the price of therapies as they directly impact patient’s out-of-pocket costs and deductible limits. Our examination looked at drug cost of PV therapies and found that prednisone has a low cost that continues to trend lower over the timeframe reviewed. Although the immediate upfront medication cost of prednisone is favorable, systemic corticosteroid use has notable hidden costs that may become a burden on the health care system. The management of adverse effects requiring specialist care and costs of concurrent prophylactic medications may make long term corticosteroid use expensive [8]. A timely transition to corticosteroid sparing immunosuppressant therapies reduces this potential and minimally increases drug costs. Methotrexate and azathioprine have similar drug costs to prednisone, whereas mycophenolate and dapsone are only slightly more costly (Table 1). Of note, the costs associated with corticosteroid-sparing immunosuppressant therapies analyzed do not account for the price of required laboratory safety monitoring. Immunoglobulin-based therapies may be viewed as cost prohibitive by some payers, but Heelan et al. found that rituximab reduced the costs associated with the treatment of pemphigus and pemphigoid. Rituximab has decreased in price (-16.90%) whereas IVIG has increased in price (+14.92%) over the

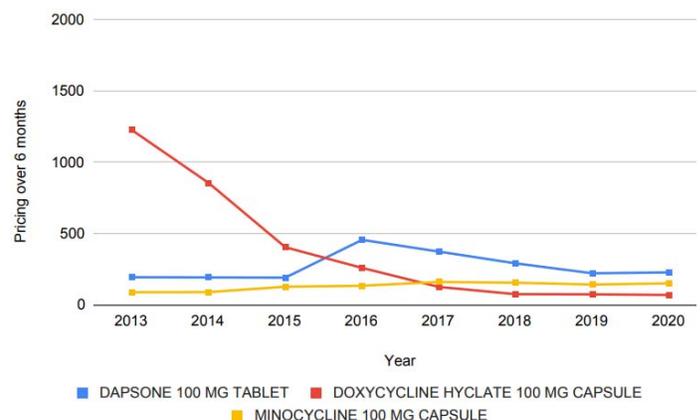


Figure 2. Cost of six months of treatment with systemic anti-inflammatory agents between December 2013 and February 2020. Doses were based on international guidelines for pemphigus vulgaris treatment: dapsone 100mg/day, doxycycline hyclate 100mg BID, minocycline 100mg BID [5].

studied period (**Table 1**). The optimal time to transition from immunosuppressants to rituximab remains unclear and future investigations into the cost effectiveness of these therapies would be useful to help guide management.

The limitations of this study include the unavailability of NADAC data on immunoglobulin treatments, including rituximab and IVIG. The costs of rituximab and IVIG obtained from the Magellan Medical Pharmacy Trend Reports may exclude the ancillary costs of infusion, but this could not be confirmed. It should be recognized there are several additional costs factors that contribute to infusion therapies including costs of co-administered drugs, wages for infusion service labor, and infusion supplies [9], but this is beyond the scope of this discussion.

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Conclusion

In conclusion, there is an expanding arsenal of PV treatments but the prices of treatment remain cost-prohibitive for many. All discussed medication prices are those prior to the COVID-19 pandemic and future studies may be warranted to determine its implications on treatment costs. Additional studies on pharmacoeconomics that incorporate cost-effectiveness in PV treatment will be necessary as novel targeted agents continue to shape treatment of autoimmune bullous diseases.

Potential conflicts of interest

Dr. Krase has consulted for AbbVie and received an honorarium.