Provider burden associated with apremilast adverse events

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Synopsis

- In the US, more than 7.5 million adults (≥20 years of age) have psoriasis[1]
- Clinical trials have demonstrated apremilast safety and efficacy, yet the treatment also resulted in reports of adverse events (AEs), such as diarrhea, nausea, and headache[2-7]
- Management of AEs may increase healthcare provider (HCP) burden, which has been linked to provider burnout and concerns for patient safety[8]
- To date, there remains limited real-world data regarding the use of apremilast, the influence of AEs, and the burden of AEs on HCPs in the US

Objectives

This study aimed to:

- Describe real-world characteristics of providers who treat patients with psoriasis in the US
- Characterize the provider-reported healthcare resource use burden associated with AEs experienced by apremilast users

Methods

Study design

- A multicenter physician survey
- HCPs were recruited from the Dermatology Provider Extended Network and included physicians who:
  - Managed and treated the targeted patient population as a part of routine care
  - Self-identified as interested and able to participate
  - Could participate in research approved by a central IRB
- HCPs were surveyed regarding patients who:
  - Were aged ≥18 years with a diagnosis of plaque psoriasis
  - Were treated with apremilast on or after January 1, 2018
  - Had ≥3 months of clinical history following apremilast initiation

Outcomes

- HCP and practice characteristics
- Resource utilization to manage apremilast treatment and AEs
  - Calls/messages received
  - Additional visits (in-office or virtual)
- Assessment of treatment-related AEs
  - Physician severity rating
  - Common Terminology Criteria for Adverse Events (CTCAE) grade
  - Date of onset

Statistical analysis

- All variables were summarized using descriptive statistics

Results

- The study recruited 47 HCPs nationwide (**Table 1**)
- All HCPs were dermatologists and had been practicing for a mean 12.1 (standard deviation [SD] 9.3) years
- On average, HCPs identified 48.6 (SD 61.4) patients who met study eligibility criteria

Table 1. HCP and practice characteristics

Characteristics	
Medical specialty, n (%)	
Dermatology	47 (100.0)
Years of specialty practice, mean (SD)	12.1 (9.3)
Number of patients with PsO managed within last 2 years	
Mean (SD)	712.3 (884.3)
Number of patients treated with apremilast	
Mean (SD)	93.9 (166.7)
Number of patients eligible for study inclusion	
Mean (SD)	48.6 (61.4)
Management of AEs during treatment,[a] n (%)	
MD/DO	46 (97.9)
NP	5 (10.6)
PA	8 (17.0)
RN	1 (2.1)
US region of practice, n (%)	
Northeast	14 (29.8)
Midwest	6 (12.8)
South	14 (29.8)
West	13 (27.7)
Practice setting, n (%)	
Urban	13 (27.7)
Suburban	32 (68.1)
Rural	2 (4.3)
Practice type, n (%)	
Solo practice	9 (19.1)
Small private community practice[b]	17 (36.2)
Medium-sized private community practice[c]	9 (19.1)
Large private community practice[d]	8 (17.0)
Academic medical center	3 (6.4)
Affiliated teaching hospital	1 (2.1)

[a]Not mutually exclusive.
[b]2-5 physician practice.
[c]6-10 physician practice.
[d]>10 physician practice.
AE, adverse event; DO, doctor of osteopathic medicine; HCP, healthcare provider; MD, medical doctor; NP, nurse practitioner; PA, physician's assistant; PsO, psoriasis; RN, registered nurse; SD, standard deviation.

Adverse events

- Approximately 29.2% of patients reported an apremilast-related AE
- Complaints of diarrhea, nausea, and headache were most common and often occurred within 30 days of apremilast initiation (**Table 2**)
  - 91.5% (n = 43) of HCPs received reports of diarrhea
  - 78.7% (n = 37) of HCPs received reports of nausea
  - 55.3% (n = 26) of HCPs received reports of headache
- According to CTCAE guidelines,[9] AEs were most often grade 2 in severity among patients reporting diarrhea, nausea, and headache (**Table 2**)

Table 2. AEs experienced while receiving apremilast

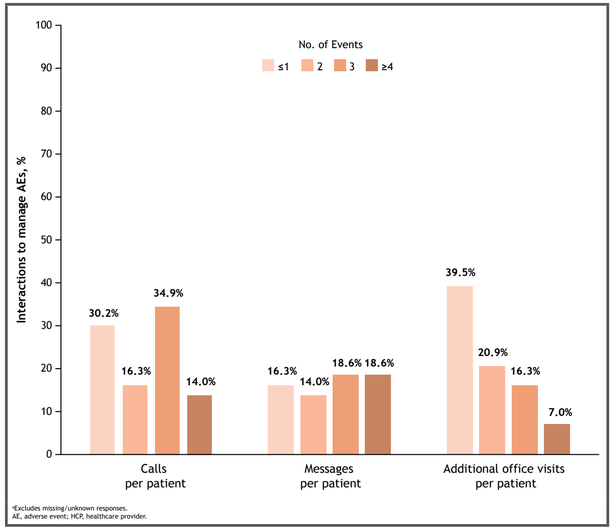
Patients reporting AE/toxicity			n (%)
Diarrhea			50 (16.2)
Nausea			42 (13.6)
Headache			15 (4.9)
Fatigue			4 (1.3)
Depression			4 (1.3)
Insomnia			1 (0.3)
Other[a]			
Weight loss			3 (1.0)
Upset stomach			2 (0.7)
Atrial fibrillation			1 (0.3)
Irritable			1 (0.3)
Physicians receiving reports of APR-related AEs			**n (%)**
Diarrhea			43 (91.5)
Nausea			37 (78.7)
Headache			26 (55.3)
None of the above			1 (2.1)
Time to AE occurrence, n (%)	**Diarrhea**	**Nausea**	**Headache**
1-30 days	41 (87.2)	33 (70.2)	21 (44.7)
31-60 days	22 (46.8)	16 (34.0)	13 (27.7)
61-90 days	12 (25.5)	10 (21.3)	8 (17.0)
Highest CTCAE grade, n (%)	**Diarrhea**	**Nausea**	**Headache**
1	13 (4.2)	14 (4.6)	1 (0.3)
2	35 (11.4)	29 (9.4)	10 (3.3)
3	6 (2.0)	6 (2.0)	6 (2.0)

[a]Not mutually exclusive.
AE, adverse event; APR, apremilast; CTCAE, Common Terminology Criteria for Adverse Events.

Burden on HCP

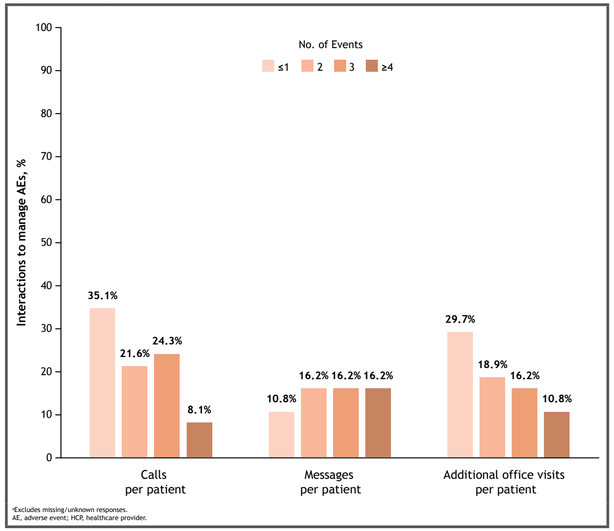
- Diarrhea management (**Figure 1**)
  - 34.9% of HCPs managed approximately 3 calls per patient
    - 88.4% of calls lasted 10 minutes or less
  - 18.6% of HCPs managed approximately 3 messages per patient
  - 39.5% of HCPs reported ≤1 additional visit
    - 48.8% of additional visits lasted 11-20 minutes
- Nausea management (**Figure 2**)
  - 35.1% of HCPs managed approximately 1 call per patient
    - 81.1% of calls lasted 10 minutes or less
  - 16.2% of HCPs managed approximately 2 messages per patient
  - 29.7% of HCPs reported ≤1 additional visit
    - 48.7% of additional visits lasted 10 minutes or less
- Headache management (**Figure 3**)
  - 26.9% of HCPs managed approximately 1 call per patient
    - 76.9% of calls lasted 10 minutes or less
  - 23.1% of HCPs managed approximately 3 messages per patient
  - 42.3% of HCPs reported ≤1 additional visit
    - 46.2% of additional visits lasted 10 minutes or less

Figure 1. HCP-reported burden[a] due to diarrhea



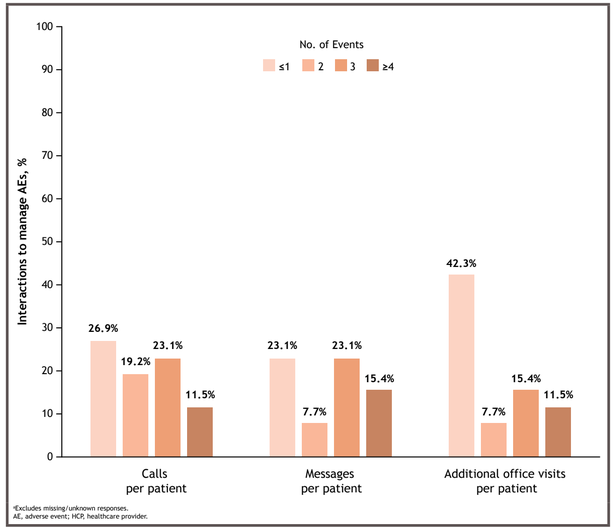
[a]Excludes missing/unknown responses.
AE, adverse event; HCP, healthcare provider.

Figure 2. HCP-reported burden[a] due to nausea



[a]Excludes missing/unknown responses.
AE, adverse event; HCP, healthcare provider.

Figure 3. HCP-reported burden[a] due to headache



[a]Excludes missing/unknown responses.
AE, adverse event; HCP, healthcare provider.

Conclusions

- This cross-sectional survey study provides insight into clinical practice patterns and treatment outcomes in US dermatology practices
- HCPs reported frequent complaints of diarrhea, nausea, and headache following apremilast initiation, which resulted in additional time and resources dedicated to AE management
- More research is needed to further confirm and quantify the economic impact of apremilast-related AE burden on patients and HCPs

References

1. Armstrong A, et al. *JAMA Dermatol*. 2021;157:940-946.
2. Papp K, et al. *Lancet*. 2012;380:738-746.
3. Augustin M, et al. *JEADV*. 2021;35:123-134.
4. Cetkovská P, et al. *Adv Ther*. 2023;40:1787-1802.
5. Jullien D, et al. *Dermatol Ther*. 2023;13:1361-1376.
6. Jonak C, et al. *Ther Adv Chronic Dis*. 2023;14:1-11.
7. Armstrong AW, et al. *J Am Acad Dermatol*. 2023;88:29-39.
8. Gupta K, et al. *J Patient Saf*. 2022;18(6):531-538.
9. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events. (CTCAE) v5.0. 2017. https://ctep.cancer.gov/.

Acknowledgments

- This study was sponsored by Bristol Myers Squibb
- Medical writing and editorial assistance was provided by Michon Jackson, PhD, of Peloton Advantage, LLC, an OPEN Health company, funded by Bristol Myers Squibb

Disclosures

- **LS:** Speaker: AbbVie, Amgen, Incyte, Janssen, and Lilly
- **YW:** Employee and shareholder: Bristol Myers Squibb
- **VP:** Employee and shareholder at time of study: Bristol Myers Squibb
- **DG, DL, JS, CO, MA,** and **BF:** Employees: Cardinal Health

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Presented at the 44th Annual Fall Clinical Dermatology Conference; October 24-27, 2024; Las Vegas, NV
This is an encore of the 2024 European Academy of Dermatology & Venereology (EADV) poster.

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