PO-4350

Clinical burden and healthcare resource utilisation in patients with generalized pustular psoriasis: A claims database study

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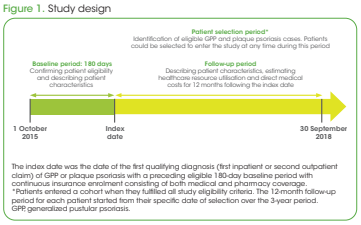
Background

- Generalized pustular psoriasis (GPP) is defined as a rare, neutrophilic skin disease. It is characterised by episodes of widespread eruption of sterile, macroscopically visible pustules that can occur with or without systemic inflammation and with or without plaque psoriasis[1–4]
- Recent data indicate that GPP is clinically, genetically and histologically distinct from plaque psoriasis[5–7]
  - Despite this, the treatment pathways for GPP and plaque psoriasis remain similar[2,3,5–8]
- Current treatments for GPP vary globally, ranging from conventional treatments, including cyclosporine, methotrexate and retinoids, to biologic therapies, such as infliximab[3,4,8,9]
- Conventional treatments for GPP have several safety limitations, making them inappropriate for long-term use, for example, retinoids, which are associated with dose-dependent adverse events[3,8,9]
- There are currently no approved treatments for the specific indication of GPP in the USA or Europe, highlighting an unmet need in this patient population[4]
- To date, there is limited real-world evidence characterising patients with GPP[2]
  - Prior to the International Classification of Diseases, 10th Revision (ICD-10) transition, GPP did not have its own diagnostic code and was included in ICD-9 696.1: Other psoriasis; it was therefore nearly impossible to identify patients with GPP via claims alone
- In order to better understand and evaluate the unmet needs of patients with GPP, this study aimed to describe the US clinical burden and healthcare resource utilisation (HCRU) of patients with GPP compared with those with plaque psoriasis and the general population

Methods

- Patients included in the study cohort were identified as having GPP or plaque psoriasis if they had ≥1 inpatient or 2 outpatient diagnostic code(s) for ICD-10 L40.1 or L40.0, respectively, separated by 30–365 days
  - Patients with plaque psoriasis who also had a diagnosis of GPP or palmoplantar pustulosis were excluded from the final cohorts, and cohorts were mutually exclusive. Patients with GPP who also had a diagnosis of plaque psoriasis were included in the final cohort
- The study period was from 1 October 2015 to 30 September 2018, with the first qualifying diagnosis (first inpatient or second outpatient claim) marking the index date **(Figure 1)**
- Subjects from the general population were matched 4:1 based on age and sex to those with GPP. This cohort excluded subjects with any psoriasis other than psoriatic arthritis. These subjects, as well as patients in the plaque psoriasis cohort, provided context to the GPP burden of disease and HCRU
- Patient characteristics and concomitant medication use during baseline, and dermatological medication burden for patients with 12 months' follow-up were analysed. All-cause HCRU during the 12-month follow-up was recorded for inpatient, outpatient and emergency department (ED) settings
- Treatments were identified using medical and pharmacy claims by the Healthcare Common Procedure Coding System and the National Drug Codes, respectively
- All analyses were conducted via the Aetion Evidence Platform® v3.11, using IBM® MarketScan® Research Databases[10]
  - Both Medicare and employer commercial insurance patients were included in the analysis
- All analyses were descriptive in nature; no formal comparisons were conducted

Figure 1. Study design



The index date was the date of the first qualifying diagnosis (first inpatient or second outpatient claim) of GPP or plaque psoriasis with a preceding eligible 180-day baseline period with continuous insurance enrolment consisting of both medical and pharmacy coverage.
*Patients entered a cohort when they fulfilled all study eligibility criteria. The 12-month follow-up period for each patient started from their specific date of selection over the 3-year period.
GPP, generalized pustular psoriasis.

Results

Patient population and demographics during baseline

- In total, 1175 patients with GPP, 75,494 with plaque psoriasis and 4312 in the general population matched cohort were identified. Overall, 637 patients with GPP and 38,950 patients with plaque psoriasis had the 12 months of continuous enrolment required for the follow-up period **(Figure 2)**
  - In the general population matched cohort, 2276 patients had the required 12 months of follow-up

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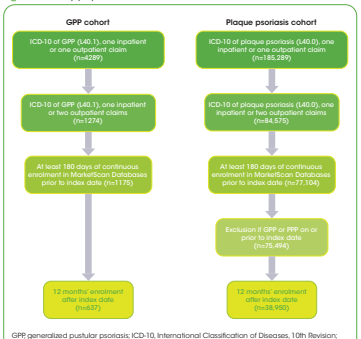

GPP, generalized pustular psoriasis; ICD-10, International Classification of Diseases, 10th Revision; PPP, palmoplantar pustulosis.

- Patients with GPP had a mean age of 52.4 years and were more likely to be female than male (63.3%) compared with the plaque psoriasis cohort in which patients had a mean age of 49.0 years, and 51.2% were female **(Table 1)**

Table 1. Patient demographics at baseline

	GPP cohort (n=1175)	Plaque psoriasis cohort (n=75,494)	General population matched cohort (n=4312)
Female	744 (63.3)	38,639 (51.2)	2724 (63.2)
Age, years, mean (SD)	52.4 (13.3)	49.0 (15.6)	46.4 (17.4)
<18 years, n (%)	15 (1.3)	2388 (3.2)	52 (1.2)
18–64 years, n (%)	1014 (86.3)	64,222 (85.1)	3696 (85.7)
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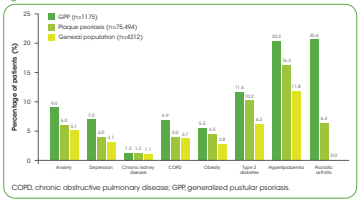
Commercial insurance (fee for service + encounter), n %	1019 (86.7)	66,559 (88.2)	3751 (87.0)
Medicare patients (Medicare + Medicare encounter), n %	156 (13.3)	8935 (11.8)	561 (13.0)

GPP, generalized pustular psoriasis; SD, standard deviation.

Comorbidities

- At baseline, patients in the GPP cohort were more likely to suffer from comorbidities than those in the plaque psoriasis and general population matched cohorts, including psoriatic arthritis (20.6% vs 6.4% and <0.1%, respectively), anxiety (9.0% vs 6.0% and 5.1%) and depression (7.0% vs 4.0% and 3.1%)
  - Other comorbidities: patients with GPP were more likely to suffer from included type 2 diabetes, hyperlipidaemia, obesity, chronic obstructive pulmonary disease and chronic kidney disease **(Figure 3)**

Figure 3. Comorbidities at baseline



COPD, chronic obstructive pulmonary disease; GPP, generalized pustular psoriasis.

Concomitant medication use at baseline

- During the baseline period, the most common class of prescription drugs for patients with GPP and plaque psoriasis was antibiotics, although the distribution of patients receiving antibiotics was higher in the GPP cohort (GPP: 45.1%; plaque psoriasis: 36.3%; **Table 2**)
- Of note, the use of opioid pain medication was higher in the GPP cohort (23.3%) than in both the plaque psoriasis (15.6%) and general population (12.4%) cohorts
- Antihypertensive, psychiatric medication and asthma medication use was also substantially higher in patients with GPP compared with the plaque psoriasis and general population cohorts **(Table 2)**

Table 2. Most common concomitant medications at baseline

Medication, n (%)	GPP cohort (n=1175)	Plaque psoriasis cohort (n=75,494)	General population matched cohort (n=4312)
Antibiotics	530 (45.1)	27,384 (36.3)	1193 (27.7)
Antihypertensives	485 (41.3)	27,249 (36.1)	1118 (25.9)
Psychiatric medication	440 (37.4)	21,540 (28.5)	902 (20.9)
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Type 2 diabetes medication	126 (10.7)	7779 (10.3)	284 (6.6)

COPD, chronic obstructive pulmonary disease; GPP, generalized pustular psoriasis.

Medication use during the 12-month follow-up period

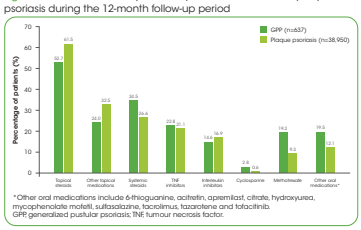
- Of the 637 patients with GPP with a full 12 months of follow-up, 446 patients (70.0%) were treated with a systemic therapy during this period (biologic, non-biologic systemic or both) compared with 62.2% of patients with plaque psoriasis (n=24,211)
- A total of 292 patients with GPP (45.8%) who completed follow-up were treated with combination therapies (topical and/or biologics and/or non-biologics) compared with 42.7% of patients with plaque psoriasis (n=16,619) **(Table 3)**
- Patients with GPP were more likely to be treated with a non-biologic systemic therapy only than patients with plaque psoriasis (13.2% vs 7.2%, respectively); however, the distribution of patients treated with a biologic monotherapy in each cohort was similar (GPP: 11.0%; plaque psoriasis: 12.3%)
  - Patients with plaque psoriasis were more likely to be treated with a topical medication only compared with patients with GPP (23.9% vs 15.7%) **(Table 3)**
- Of the biologic therapies, tumour necrosis factor inhibitors were the most commonly used in both the GPP and plaque psoriasis cohorts (GPP: 22.8%; plaque psoriasis: 21.1%) **(Figure 4)**
- Of the non-biologic therapies, methotrexate was the most commonly used oral therapy in both the GPP and plaque psoriasis cohorts (GPP: 19.2%; plaque psoriasis: 9.3%; **Figure 4**)

Table 3. Total treatments received during the 12-month follow-up period on or after the index date

Medication, n (%)	GPP cohort (n=637)	Plaque psoriasis cohort (n=38,950)
No treatment	91 (14.3)	5445 (14.0)
Topical only	100 (15.7)	9294 (23.9)
Non-biologic systemic* monotherapy	84 (13.2)	2797 (7.2)
Biologic monotherapy†	70 (11.0)	4795 (12.3)
Topical + non-biologic systemic	115 (18.1)	7060 (18.1)
Topical + biologic	58 (9.1)	4341 (11.1)
Non-biologic systemic + biologic	56 (8.8)	1950 (5.0)
Topical + non-biologic systemic + biologic	63 (9.9)	3268 (8.4)

*Non-biologic systemic therapies include 6-thioguanine, acitretin, apremilast, cyclosporine (excluding Restasis ophthalmic route), hydroxyurea, methotrexate, mycophenolate mofetil, sulfasalazine, tacrolimus (oral route only) and tofacitinib.
†Biologic monotherapies include adalimumab, certolizumab pegol, etanercept, infliximab, golimumab, ustekinumab, secukinumab, brodalumab, ixekizumab, guselkumab and abatacept.
GPP, generalized pustular psoriasis.

Figure 4. Medication use by class for patients with GPP and plaque psoriasis during the 12-month follow-up period



*Other oral medications include 6-thioguanine, acitretin, apremilast, citrate, hydroxyurea, mycophenolate mofetil, sulfasalazine, tacrolimus, tazarotene and tofacitinib.
GPP, generalized pustular psoriasis; TNF, tumour necrosis factor.

All-cause HCRU during the 12-month follow-up period

- Overall, patients with GPP had more outpatient visits than those with plaque psoriasis and the general population (mean visits, GPP: 24.9; plaque psoriasis: 21.0; general population: 13.1; **Table 4**)
- A higher distribution of patients with GPP required inpatient stays (12.2%) compared with the plaque psoriasis (6.5%) and general population (6.2%) cohorts **(Table 4)**
  - The mean duration of inpatient stays was also longer in the GPP cohort (11.5 days) compared with the plaque psoriasis (7.1 days) and general population (6.7 days) cohorts **(Table 4)**
- A higher distribution of patients with GPP required ED visits compared with the plaque psoriasis and general population cohorts (24.6% vs 20.0% and 18.0%, respectively; **Table 4**)

Table 4. Overall HCRU during the 12-month follow-up period

HCRU	GPP cohort (n=637)	Plaque psoriasis cohort (n=38,950)	General population matched cohort (n=2276)
All-cause outpatient visits, n (%)	637 (100.0)	38,950 (100.0)	2028 (89.1)
Median visits (IQR)	17 (9–32)	14 (8–25)	7 (3–15)
Mean visits (SD)	24.9 (26.1)	21.0 (24.2)	13.1 (18.8)
All-cause inpatient visits, n (%)	78 (12.2)	2523 (6.5)	142 (6.2)
Median visits (IQR)*	1 (1–2)	1.0 (1–1)	1.0 (1–1)
Mean visits (SD)*	1.9 (1.5)	1.3 (0.8)	1.2 (0.7)
Duration of inpatient stays, days			
Median duration (IQR)	5 (3–12)	4 (3–7)	4 (3–7)
Mean duration (SD)	11.5 (16.0)	7.1 (10.3)	6.7 (7.8)
All-cause ED visits, n (%)	157 (24.6)	7778 (20.0)	409 (18.0)
Median visits (IQR)	1 (1–2)	1 (1–2)	1 (1–2)
Mean visits (SD)	2.0 (1.7)	1.7 (2.1)	1.7 (1.1)

*Distributions represent only those patients who had inpatient visits.
ED, emergency department; GPP, generalized pustular psoriasis; HCRU, healthcare resource utilisation; IQR, interquartile range; SD, standard deviation.

Discussion

- This study summarises the clinical characteristics of 1175 patients with GPP in a real-world setting in the USA, including 637 who were included in the 12-month follow-up analysis
- This study showed that during the baseline period, patients with GPP had a numerically higher prevalence of multiple comorbidities, and during follow-up had differing concomitant medication burden compared with patients with plaque psoriasis. This suggests that patients with GPP have a different clinical profile to those with plaque psoriasis
- HCRU was numerically higher in patients with GPP than in patients with plaque psoriasis and the general population, suggesting that GPP and associated comorbidities result in higher healthcare needs in this patient population
  - The skew of the mean values compared with the median values meant that the mean values were upweighted by the patients with the highest burden of disease
- This study is not without limitations. The study used administrative claims data, which are collected for the purpose of billing and reimbursement as opposed to research. These data may have coding errors and lack detailed clinical information
  - Data for medications are generally considered to be accurate, reflecting the medication the patient received at the pharmacy; however, they do not include treatments that are bought over the counter
- The increased HCRU and distribution of comorbidities in patients with GPP in this study compared with those with plaque psoriasis highlight an unmet need in this patient population

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Disclosures

This study was funded by Boehringer Ingelheim. At the time of the study, N Kotowsky, D Singer, R Gao and AK Golembesky* were full-time employees of Boehringer Ingelheim. EM Garry is employed by Aetion, contracted by Boehringer Ingelheim.

*AK Golembesky is now employed by GlaxoSmithKline.

Acknowledgements

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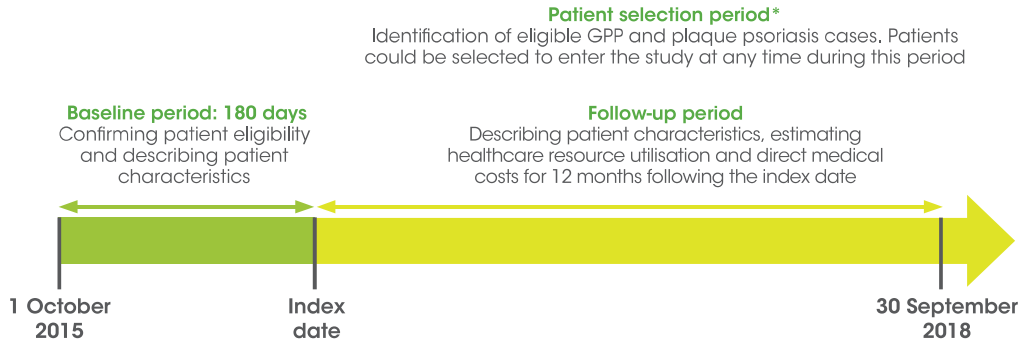

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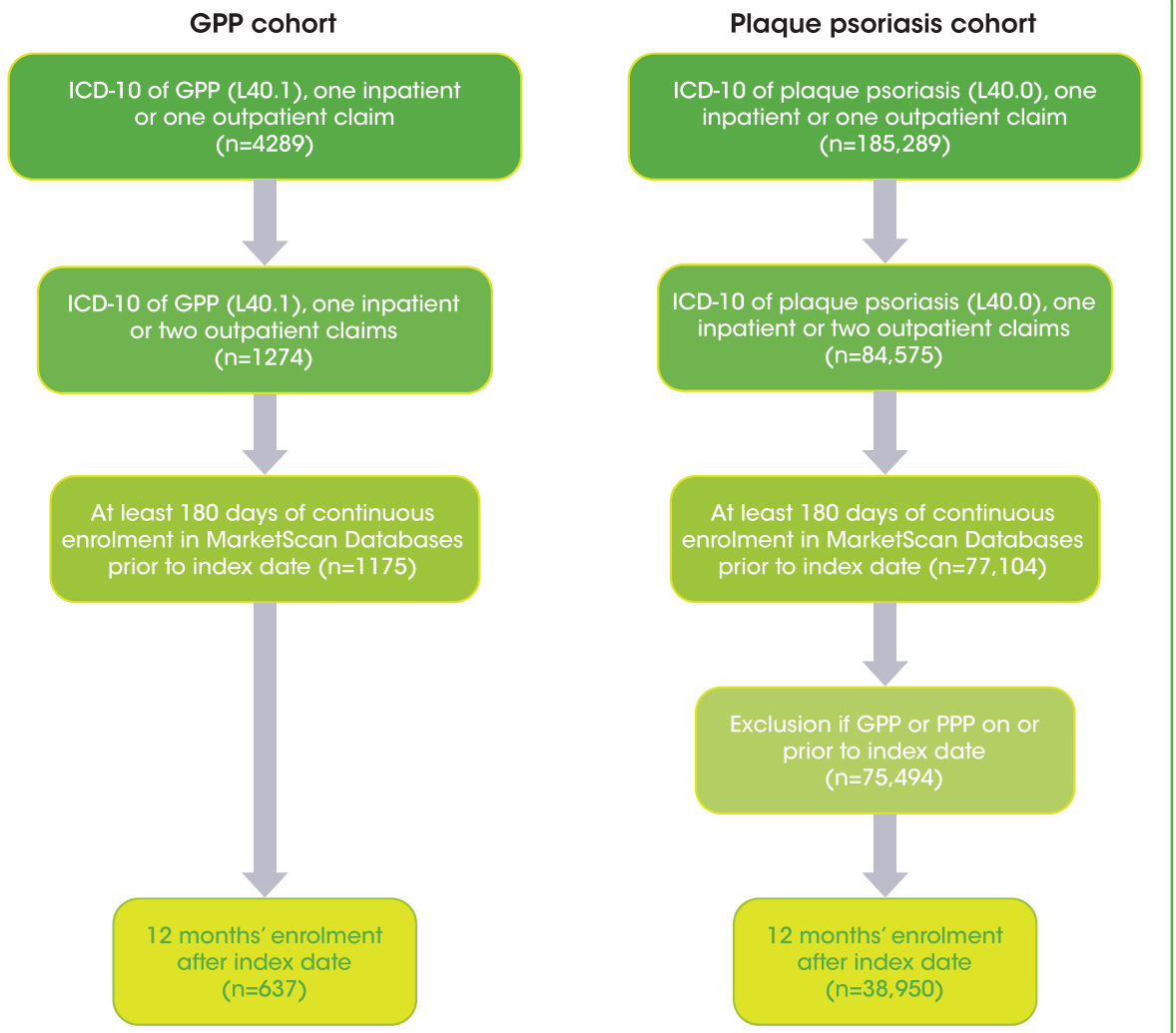

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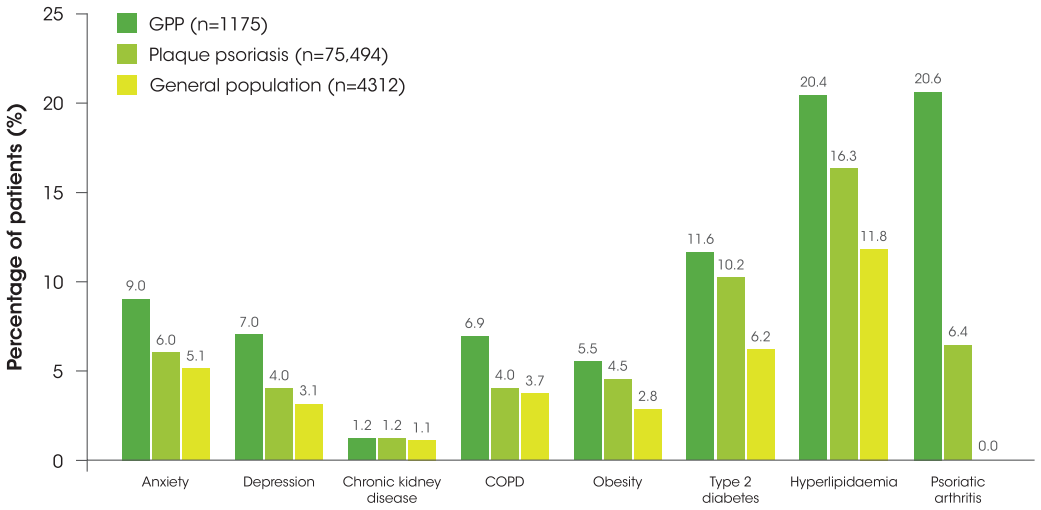

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- Of the non-biologic therapies, methotrexate was the most commonly used oral therapy in both the GPP and plaque psoriasis cohorts (GPP: 19.2%; plaque psoriasis: 9.3%; **Figure 4**)

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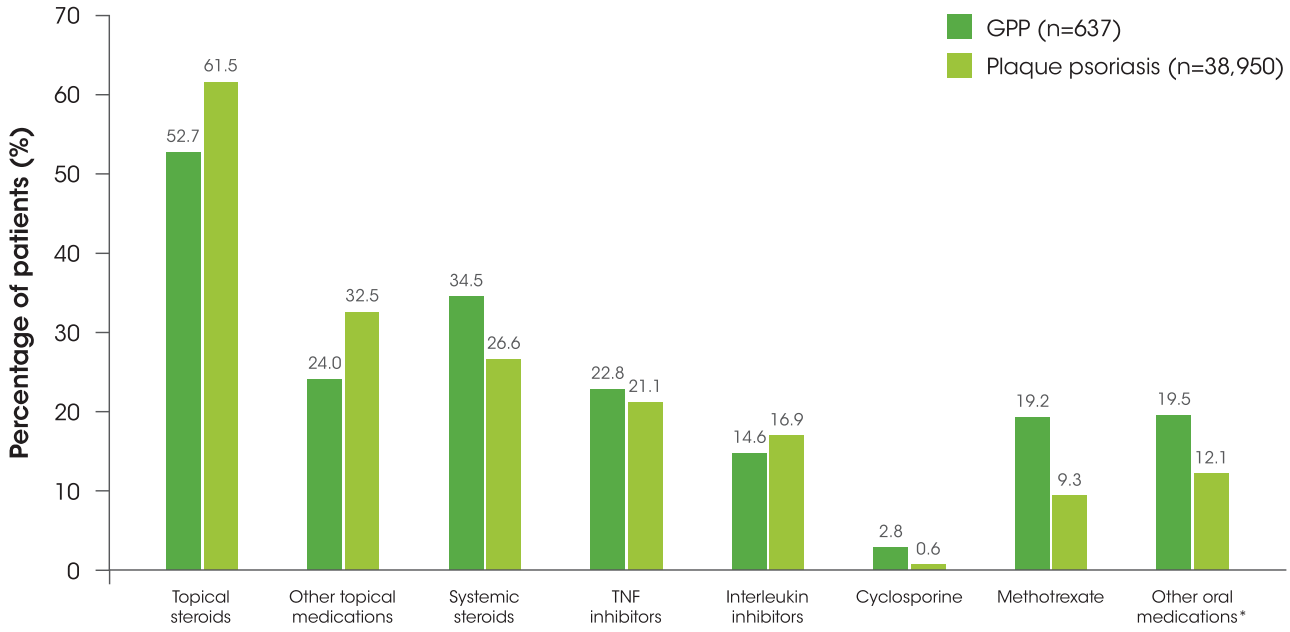

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GPP, generalized pustular psoriasis; TNF, tumour necrosis factor.

All-cause HCRU during the 12-month follow-up period

- Overall, patients with GPP had more outpatient visits than those with plaque psoriasis and the general population (mean visits, GPP: 24.9; plaque psoriasis: 21.0; general population: 13.1; **Table 4**)
- A higher distribution of patients with GPP required inpatient stays (12.2%) compared with the plaque psoriasis (6.5%) and general population (6.2%) cohorts **(Table 4)**
  - The mean duration of inpatient stays was also longer in the GPP cohort (11.5 days) compared with the plaque psoriasis (7.1 days) and general population (6.7 days) cohorts **(Table 4)**
- A higher distribution of patients with GPP required ED visits compared with the plaque psoriasis and general population cohorts (24.6% vs 20.0% and 18.0%, respectively; **Table 4**)

Table 4. Overall HCRU during the 12-month follow-up period

HCRU	GPP cohort (n=637)	Plaque psoriasis cohort (n=38,950)	General population matched cohort (n=2276)
All-cause outpatient visits, n (%)	637 (100.0)	38,950 (100.0)	2028 (89.1)
Median visits (IQR)	17 (9–32)	14 (8–25)	7 (3–15)
Mean visits (SD)	24.9 (26.1)	21.0 (24.2)	13.1 (18.8)
All-cause inpatient visits, n (%)	78 (12.2)	2523 (6.5)	142 (6.2)
Median visits (IQR)*	1 (1–2)	1.0 (1–1)	1.0 (1–1)
Mean visits (SD)*	1.9 (1.5)	1.3 (0.8)	1.2 (0.7)
Duration of inpatient stays, days			
Median duration (IQR)	5 (3–12)	4 (3–7)	4 (3–7)
Mean duration (SD)	11.5 (16.0)	7.1 (10.3)	6.7 (7.8)
All-cause ED visits, n (%)	157 (24.6)	7778 (20.0)	409 (18.0)
Median visits (IQR)	1 (1–2)	1 (1–2)	1 (1–2)
Mean visits (SD)	2.0 (1.7)	1.7 (2.1)	1.7 (1.1)

*Distributions represent only those patients who had inpatient visits.
ED, emergency department; GPP, generalized pustular psoriasis; HCRU, healthcare resource utilisation; IQR, interquartile range; SD, standard deviation.

Discussion

- This study summarises the clinical characteristics of 1175 patients with GPP in a real-world setting in the USA, including 637 who were included in the 12-month follow-up analysis
- This study showed that during the baseline period, patients with GPP had a numerically higher prevalence of multiple comorbidities, and during follow-up had differing concomitant medication burden compared with patients with plaque psoriasis. This suggests that patients with GPP have a different clinical profile to those with plaque psoriasis
- HCRU was numerically higher in patients with GPP than in patients with plaque psoriasis and the general population, suggesting that GPP and associated comorbidities result in higher healthcare needs in this patient population
  - The skew of the mean values compared with the median values meant that the mean values were upweighted by the patients with the highest burden of disease
- This study is not without limitations. The study used administrative claims data, which are collected for the purpose of billing and reimbursement as opposed to research. These data may have coding errors and lack detailed clinical information
  - Data for medications are generally considered to be accurate, reflecting the medication the patient received at the pharmacy; however, they do not include treatments that are bought over the counter
- The increased HCRU and distribution of comorbidities in patients with GPP in this study compared with those with plaque psoriasis highlight an unmet need in this patient population

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Disclosures

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