

EFFISAYIL OBSERVE:

A real-world descriptive study of patients with generalized pustular psoriasis (GPP) in the USA

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Objective

To describe the real-world disease burden, treatment patterns, and healthcare resource utilization (HCRU) among patients with GPP

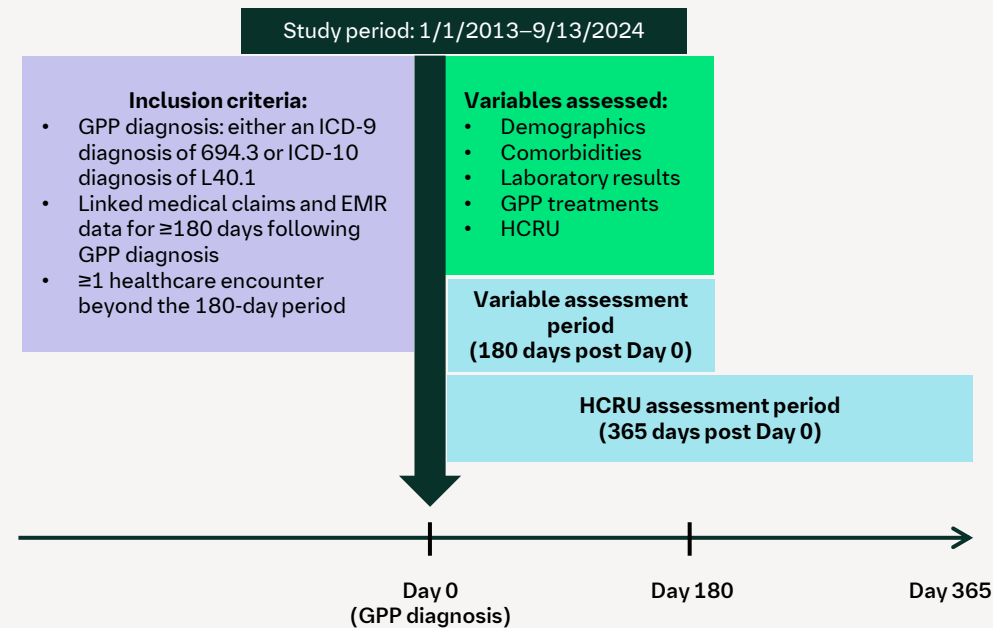
Synopsis

- GPP is a chronic, neutrophilic inflammatory disease, driven by dysregulation of the interleukin-36 pathway, and associated with systemic symptoms and high disease burden^{1,2}
- The estimated prevalence of GPP in the USA is 0.9 per 10,000 individuals³
- Given the rarity of GPP, real-world data describing treatment patterns and HCRU associated with the disease are limited⁴
- To address this knowledge gap, the EFFISAYIL OBSERVE study collected real-world data from the medical records of a representative cohort of patients with GPP in the USA

Methods

Study design

- Non-interventional observational cohort study which analyzed retrospective real-world data from the OM1 Real-World Data Cloud (OM1, Inc., Boston, MA) of patients with a GPP diagnosis



- Patients were categorized into the following cohorts: GPP-only, GPP+PsO (GPP and comorbid plaque psoriasis [PsO]), and GPP-all (GPP-only and GPP+PsO)
- Statistical tests were performed to assess differences across subgroups (e.g. chi-square tests for categorical variables; ANOVA for continuous variables)

Results

Demographics and baseline characteristics

	GPP-all	GPP-only	GPP+PsO	P value*
Patients, n	10,313	7,022	3,291	-
Mean age (SD)	55.3 (18.0)	54.4 (18.9)	57.5 (15.6)	<.001†
Female, n (%)	6,667 (64.6)	4,554 (64.9)	2,113 (64.2)	0.521†
White, n (%)	7,971 (87.5)	5,404 (87.8)	2,567 (86.8)	0.109†
Insurance status, n (%)				
Commercial	4,114 (50.8)	2,788 (50.9)	1,326 (50.5)	
Medicare	2,703 (33.3)	1,796 (32.8)	907 (34.5)	<.001†
Medicaid	503 (6.2)	395 (7.2)	108 (4.1)	
Multiple	741 (9.1)	478 (8.7)	263 (10.0)	
Other	44 (0.5)	22 (0.4)	22 (0.8)	
Census region, n (%)				
Northeast	1,306 (12.7)	944 (13.5)	362 (11.0)	
Midwest	1,768 (17.2)	1,309 (18.7)	459 (14.0)	<.001†
South	6,103 (59.3)	4,010 (57.2)	2,093 (63.7)	
West	1,123 (10.9)	750 (10.7)	373 (11.3)	

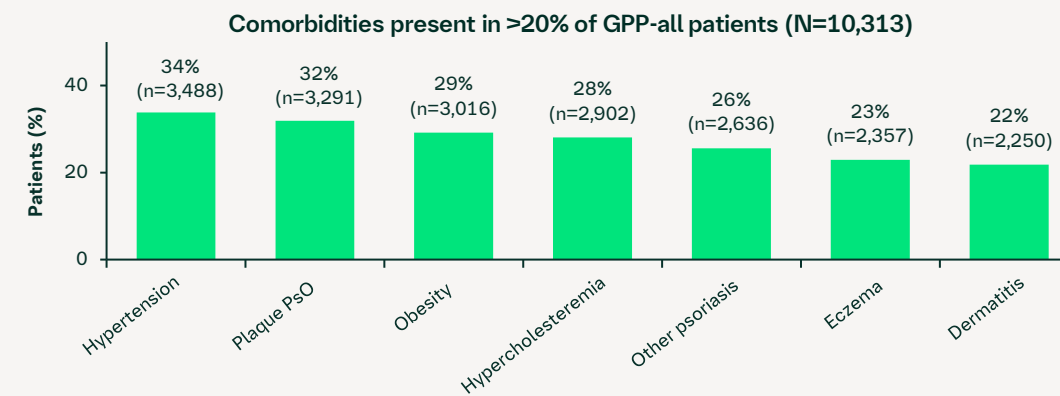
*The statistical test for difference is between the GPP+PsO vs GPP-only subgroups. †ANOVA. ‡Chi-square test.

- Some key demographic differences were identified in GPP+PsO patients compared with GPP-only patients

- While sex and ethnicity were similar across the subgroups, the mean age was older in the GPP+PsO versus the GPP-only subgroup
- Furthermore, the GPP+PsO subgroup had a higher percentage of patients from the South region and with Medicare insurance, but a lower percentage of patients with Medicaid insurance, versus the GPP-only subgroup

Comorbidities

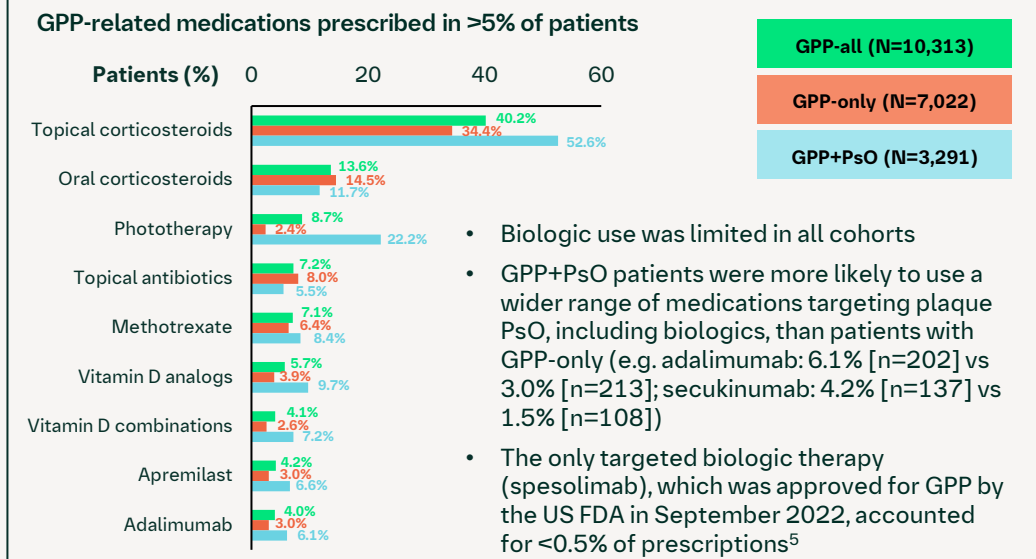
- The most common comorbidities in the GPP-all cohort were primarily metabolic/cardiovascular-related and dermatologic



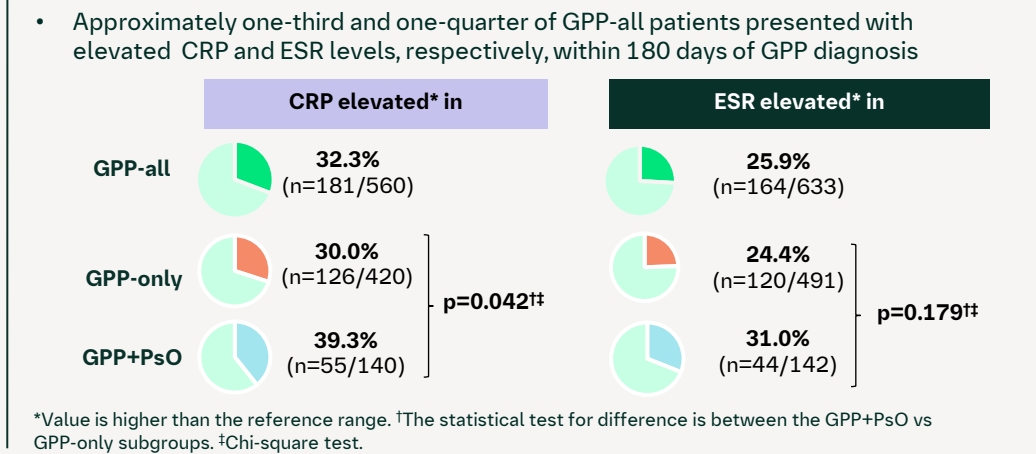
Healthcare resource utilization

	Outpatient visits	Hospital/ER admissions
GPP-all cohort	• ≥1 all-cause outpatient visit(s) within the 12-month follow-up: 98.9% (n=9,914/10,026)	• ≥1 all-cause hospitalization(s): 12.4% (n=1,244/10,026)
GPP-only vs GPP+PsO	• The GPP+PsO cohort utilized all-cause outpatient services significantly more frequently than the GPP-only subgroup	• GPP-only vs GPP+PsO hospitalization(s): 12.9% (n=876/6,809) vs 11.4% (n=368/3,217)
	• Annual median (IQR) visits per patient: 7 (4–12)	• Median (IQR) length of stay: 6 (3–12) days
	• GPP-related outpatient visit: 83.5%	• ER visits: 21.3% (n=2,132/10,026)
	• Annual median (IQR) visits per patient: 7 (4–12) vs 8 (5–15)	• Median (IQR) length of stay: 5.5 (3–12) days vs 6 (3–13) days
		• ER visits: 21.3% (n=1,449/6,809) vs 21.2% (n=683/3,217)

Treatment use



Clinical laboratory results



Conclusion

- GPP was associated with a high prevalence of cardiometabolic comorbidities (e.g. hypertension, obesity), suggesting the presence of chronic systemic inflammation as observed with elevated levels of CRP and ESR
- GPP was also associated with a substantial burden to the healthcare system, with ~20% of the GPP-all patients visiting the ER in the first 12 months since diagnosis highlighting the need for accurate and early diagnosis to reduce HCRU burden
- Data on treatment use highlight the need for the increased adoption of targeted therapies, based on improved understanding of IL-36 driven GPP pathogenesis, which can reduce the burden of disease

Abbreviations
ANOVA, analysis of variance; CRP, C-reactive protein; EMR, electronic medical record; ER, emergency room; ESR, Erythrocyte Sedimentation Rate; FDA, Food and Drug Administration; GPP, generalized pustular psoriasis; HCRU, healthcare resource utilization; ICD, International Classification of Diseases; IL, interleukin; IQR, interquartile range; PsO, psoriasis; SD, standard deviation.

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Data sharing statement
To ensure independent interpretation of clinical study results and enable authors to fulfill their role and obligations under the International Committee of Medical Journal Editors (ICMJE) criteria, Boehringer Ingelheim grants all external authors access to relevant clinical study data. In adherence with the Boehringer Ingelheim Policy on Transparency and Publication of Clinical Study Data, scientific and medical researchers can request access to clinical study data, typically, one year after the approval has been granted by major Regulatory Authorities or after termination of the development program. Researchers should use the <https://vivli.org/link-to-request-access-to-study-data> and visit <https://www.mystudywindow.com/msw/datashtaring> for further information.

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