

How Label Warnings and Precautions May Impact the Proportion of Patients with Psoriasis Initiating New Treatments

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Background

- Initiating or switching to a new treatment for psoriasis (PsO) depends on many factors such as disease severity, quality of life, comorbid conditions, and treatment history. Warnings and precautions included in medication labels present additional points of consideration.
- These warnings for approved treatments for moderate to severe plaque psoriasis often include malignancy, risks of infection inclusive of immunosuppression, and others.

Objective

- This study was conducted to assess the proportion of US patients with psoriasis seeking systemic treatment who may be impacted by common label warnings and precautions.

Study Design and Methods

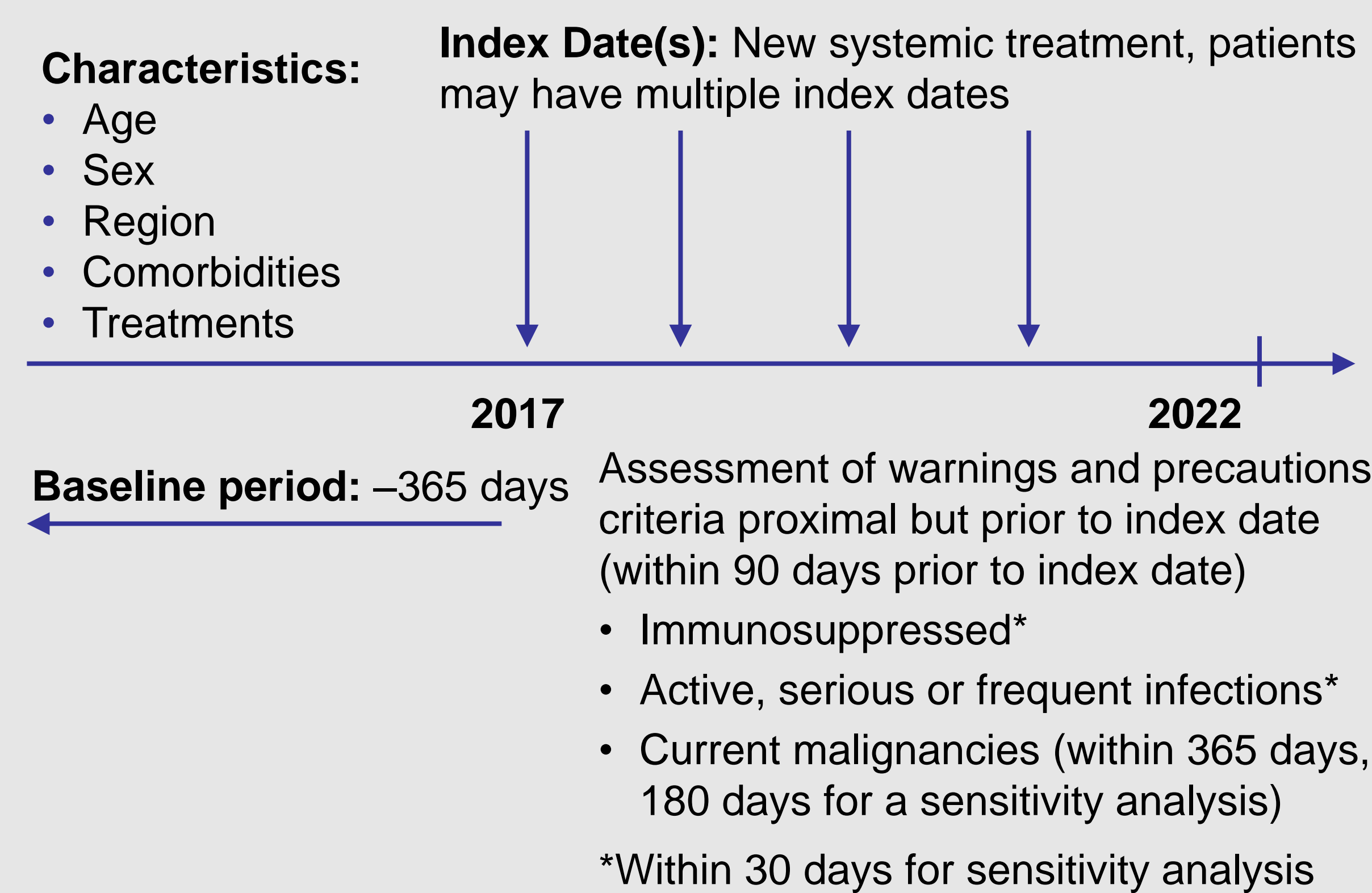
Design:

- Retrospective observational study among adults diagnosed with psoriasis (via 1 inpatient or 2 outpatient diagnosis codes) from the Optum[®] Clinformatics DataMart database.

Study Population:

- Adult patients with psoriasis who initiated new systemic treatment between September 2017 and September 2022 were included. The treatment initiation date was the index date. Baseline characteristics were defined during the 365 days prior to an index date (Figure 1).

Figure 1: Study Schema



Statistical Analysis:

- Categories related to label warnings and precautions were evaluated at the initiation of a new treatment (index date). Criteria included:
 - Using immunosuppressive medication within 90 days prior to the index date (1 dose or more of antineoplastic drug, 30 days or more of oral glucocorticoids, 90 days of transplant anti-rejection medications).¹
 - Having infections including 'active infections' and 'serious infections' (defined as hospitalized for infection including 1 inpatient claim within 90 days prior to index date [and within 30 days of index for a sensitivity analysis]) or having frequent infections, at least 6 in the past year
 - Having current malignancy including lymphoma
- Proportions were estimated for each category and overall for any of the categories.

KEY TAKEAWAYS

Over a quarter, 26.3%, of patients initiating new systemic treatment met criteria related to label warnings and precautions during the study period.

Proportions for the categories were:

- 9.4% were immunosuppressed
- 16.1% had recent infections
- 5.2% had active malignancies

Figure 2: Proportion of Systemic Treatment Initiators with Label Warnings and Precautions from 2017 to 2022 in the Optum[®] Clinformatics DataMart Database

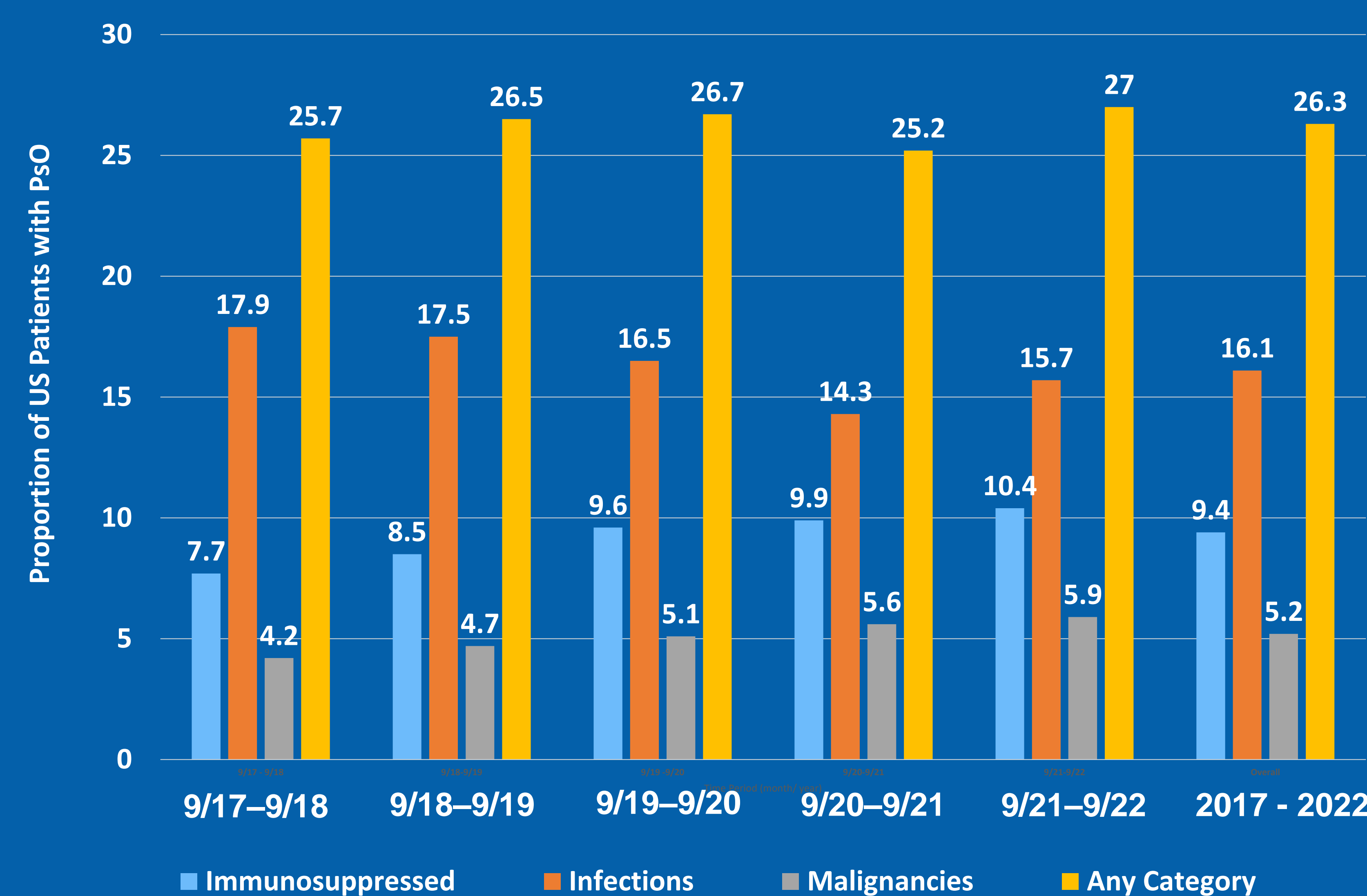
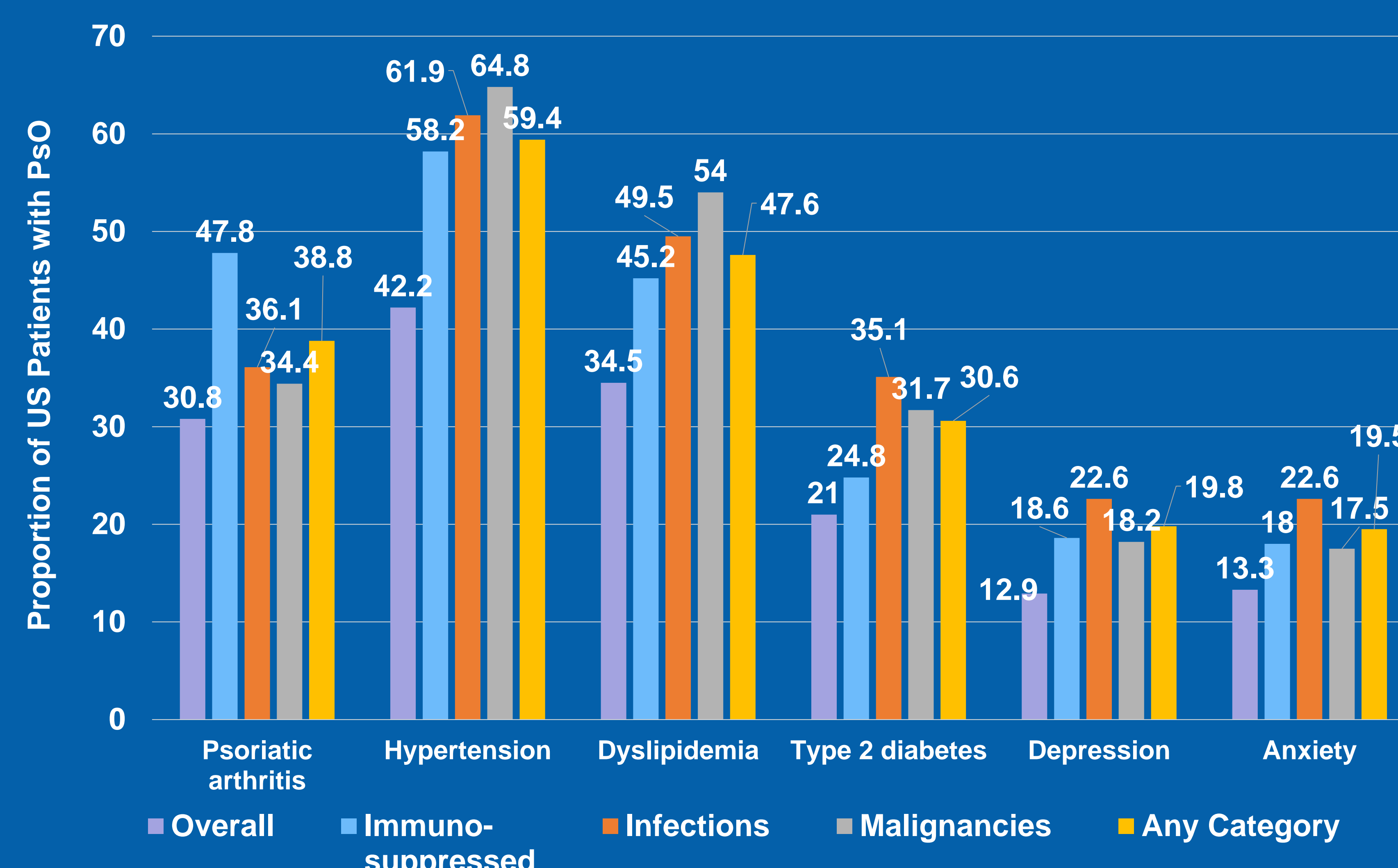


Figure 3: Baseline Comorbidities Overall and by Label Warnings and Precautions Categories



Results

- There were 125,096 new systemic treatment initiations during the study period.
- The mean age was 58.2 years and 54.5% were female (Table 1). Patients with malignancies were older.
- Overall, more patients with psoriasis had commercial insurance, however, those with criteria related to label warnings and precautions were more likely to have Medicare (Table 1). The most common comorbidities were hypertension, dyslipidemia, and psoriatic arthritis (Figure 3).

Table 1: Baseline Characteristics of Patients With Psoriasis Initiating New Systemic Treatments by Warnings and Precautions Categories

Characteristics	Overall N = 125,096	Warning and Precautions Categories			
		Immuno- suppressed n = 11,757	Infections n = 20,230	Malignancies n = 6,502	Any Category n = 32,855
Age, mean (SD)	58.2 (15.4)	64.5 (13.1)	62.0 (15.3)	68.1 (11.4)	63.2 (14.4)
Sex at birth, Female, n (%)	68,138 (54.5)	7,744 (65.9)	13,021 (64.4)	3,501 (53.8)	20,684 (63.0)
Race, White, n (%)	91,817 (73.4)	8,780 (74.7)	14,725 (72.8)	5,080 (78.1)	24,252 (73.8)
Insurance, Medicare, n (%)	53,986 (43.2)	7,746 (65.9)	11,877 (58.7)	4,534 (69.7)	20,031 (61.0)
Treatments, n (%)					
Topicals, any	65,914 (52.7)	6,093 (51.8)	11,970 (59.2)	3,736 (57.5)	18,594 (56.6)
Conventional systemics, any	49,352 (39.5)	8,626 (73.4)	9,479 (46.9)	3,436 (52.9)	17,799 (54.2)
Biologics, any	65,716 (52.5)	5,151 (43.8)	9,711 (48.0)	2,521 (38.8)	15,101 (46.0)
PDE4 Inhibitor	10,090 (8.1)	800 (6.8)	1,585 (7.8)	714 (11.0)	2,641 (8.0)

- Over the study period from 9/2017 through 9/2022, the proportion of new systemic treatment initiators that met the criteria for label warnings and precautions ranged from 25.2% to 27.0% (Figure 2). Findings for the sensitivity analysis were similar but reduced by 2%.
- The range for the proportion with immunosuppression was 7.7% to 10.4%. The range for the proportion with infections was 14.3% to 17.9% and that for those with malignancies was 4.2% to 5.9% (Figure 2).

Conclusions

- This study highlights that approximately a quarter of systemic treatment initiators with psoriasis meet the criteria related to label warnings and precautions in real-world clinical practice. These factors should be considered when selecting new treatments.

References

- Wallace BI, et al. Prevalence of Immunosuppressive Drug use among Commercially Insured US adults, 2018-2019. *JAMA Network Open* 2021;4(5):e214920

Disclosures

This study was funded by Amgen. RL has received honoraria as a principal investigator, scientific advisor, or speaker for AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers-Squibb, Dermavant, Dermira, Eli Lilly, GlaxoSmithKline, Janssen, Leo Pharma, Novartis, Ortho Dermatologics, Pfizer, Sanofi -Genzyme, Sun Pharma, and UCB Pharma. SJ, JM, KKO, CD are employees and own stock in Amgen; ML is an employee of Mount Sinai; has received research funds from AbbVie, Amgen Inc., Arcutis, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen, LEO Pharma, Ortho Dermatologics, Pfizer, and UCB; and is a consultant for Aditum Bio, Allergan, Almirall, Arcutis, Avotres Therapeutics, BirchBioMed, BMD Skincare, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corona, Dermavant Sciences, Evelo; Facilitate International Dermatologic Education, Foundation for Research and Education in Dermatology, Inozyme Pharma, Kyowa Kirin, LEO Pharma, Meiji Seika Pharma, Menlo, Mitsubishi, NeuroDerm, Pfizer, Promius/Dr. Reddy's Laboratories, Serono, Theravance, and Verrica.

For further information on the study, scan the QR code or follow the URL:
https://contents-amgen.com/prd/user-screen.html?content_id=333

