Summit on Psoriasis

Findings from the AMCP Market Insights Program

Introduction

In the last 20 years, the dermatology space has gained increasing attention, in part due to advances in therapeutics and improved outcomes across dermatologic diseases. Scientific advances have led to a better understanding of immunology and, particularly, how this pertains to the skin. The recent focus on the importance of patient-reported outcomes (PROs) provides an additional lens by which to demonstrate the efficacy of novel therapeutic interventions, revealing the impact skin diseases have on patients' lives and the dramatic effect of improving skin conditions.

On December 14-15, 2017, 13 clinicians and executives representing health plans, integrated delivery systems, pharmacy benefit managers, and employers convened in Arlington, Virginia as part of the Academy of Managed Care Pharmacy (AMCP) Market Insights Summit on the management of psoriasis. Summit attendees explored current management of psoriasis, identified opportunities for improvement, and offered potential solutions that may help guide future approaches to providing access to effective, innovative care while containing pharmaceutical costs. This report summarizes the key considerations of the participating stakeholders. The treatment of patients with psoriasis presents numerous challenges to managed care organizations.

Summit participants identified key challenges that need to be addressed to better support and manage the diagnosis and treatment of psoriasis:

- The high cost of specialty therapies, including biologics, used to treat this disorder contributes to the overall specialty drug trend.
- The rapid influx of new biologic agents and lack of well-defined treatment guidelines for using them hinders a scientific foundation for managing pharmacy and medical benefits.
- Questions exist regarding the definition of "moderate to severe" psoriasis based on current guidelines.[1]
- There is a lack of consensus on which disease severity assessment tool is most useful in practice.
- A growing body of evidence appears to show a link between psoriasis and serious comorbidities,[2-8] which may begin to influence the urgency of managing patients with moderate to severe disease with biologics.

Several new biologic medications have been approved by the Food and Drug Administration (FDA) for the treatment of moderate to severe psoriasis. The Summit's payer experts stated that additional data and evidence are still needed to support updating medical policies to include newer treatments due to their unclear clinical superiority compared with current standards of care.

Biosimilars have the potential to bring cost savings to the system and patients, especially the TNF class. However, lingering patent litigation limits the effect of these useful medications.[9]

Psoriasis and Its Effect on Serious Complications: Mounting Evidence

Psoriasis is increasingly recognized as a systemic autoimmune disease, in which genes and loci (e.g., TNRAIP3, ApoE4, PSORS2/3/4, and CDKAL1) overlap with other cardiometabolic disorders, including diabetes and cardiovascular disease.[10] The risk of comorbidity seems to increase with the severity of the psoriasis symptoms.[5]

For example, a 40-year-old patient with severe psoriasis has a 2.7-fold higher risk for cardiovascular mortality than the general population.[11] Data from the United Kingdom on cardiometabolic disease indicates that patients with severe psoriasis symptoms died about 5 years earlier than controls.[12] Patients with lesions covering at least 10% of their body surface area (BSA) had an 80% higher probability of death over 4 years, independent of risk factors.[2-8] Mediating factors include Th1/17 inflammation, increased oxidative stress associated with epidermal proliferation, and angiogenesis.[10,11]

In addition to metabolic syndrome and cardiovascular disease,[2,4,13,14] patients with psoriasis are at higher risk for mood disorders,[3] Crohn's disease,[6] chronic kidney disease,[15] and T-cell lymphoma.[16]

Researchers found that in patients with psoriasis, effective treatment of symptoms with TNF inhibitors and methotrexate also lowered cardiovascular risk.[17-19] Several randomized controlled trials are underway to determine whether treatment of psoriasis that targets the inflammation will lower the risk of inflammatory-based complications, such as cardiovascular disease.

The comorbidities associated with psoriasis may also directly relate to lower quality of life (QoL) scores based on 36-Item Short Form Health Survey (SF-36) physical

and mental functioning. In terms of physical functioning, patients with psoriasis yielded lower SF-36 scores than patients with depression, myocardial infarction, type 2 diabetes, and arthritis.[20] Likewise, on mental functioning domains, psoriasis was associated with poorer scores compared with the above-mentioned conditions, in addition to congestive heart failure.[20]

Improvements in psoriasis symptoms (determined using the Psoriasis Activity and Severity Index [PASI]) resulted in improved health-related QoL.[21] In fact, patients achieving a PASI score of 90 or above (i.e., ≥ 90% improvement in symptoms, according to this scoring system) experienced the greatest increases in QoL scores (as measured by Dermatology Life Quality Index [DLQI]) in a clinical study of ixekizumab. Worsening psoriasis symptoms resulted in a 2-fold negative effect on these QoL scores.[22] This may also serve as a factor in decisions about modifying or continuing a specific treatment regimen and emphasizing the importance of maintaining a clinical response.[23]

In time, comorbid risk factors may play a role not only in choosing the initial psoriasis treatment but also in the selection of preventive therapies. For example, in a patient with few comorbid risk factors, methotrexate remains a first-line treatment choice. However, if obesity, metabolic syndrome, or diabetes are present, methotrexate may no longer be considered as a first-line option, owing to the risk for complications (e.g., cirrhosis).

Summit Insights: Challenges in Gauging Psoriasis Symptom Status and Improvement

The Summit participants raised an important question: is it better to focus treatment plans for patients with psoriasis to improve symptoms or to prevent comorbidities? Without a broadly accepted treatment guideline or algorithm that elucidates these considerations, payers and physicians are challenged to develop aligned treatment and coverage determination pathways.

Physician Perspectives. The implications of disease comorbidities are not yet incorporated into a holistic measurement of patient status or improvement. However, the prevailing challenge is more basic: several psoriasis severity assessment tools are available to specifically assess disease status and changes, but little consensus exists among clinicians and payers regarding their standard use in practice.

The FDA utilizes PASI as the standard measure in clinical trials for psoriasis treatments, but it is not generally used in clinical practice, owing to the complexity of its erythema, scaling, and induration ratings over 4 anatomical regions. The PASI score can range from 0 to 72, but a PASI score of more than 10 is generally considered to indicate moderate to severe symptoms. A 75% reduction in the PASI score (i.e., PASI 75) is the current benchmark of primary endpoints for clinical trials of psoriasis. While achieving higher PASI scores indicates the presence of more severe psoriasis at baseline, it is difficult for patients or doctors to describe the clinical severity for any specific PASI number. Attempts have been made to address this problem by providing descriptions of psoriasis severity using other numerous evaluation systems.

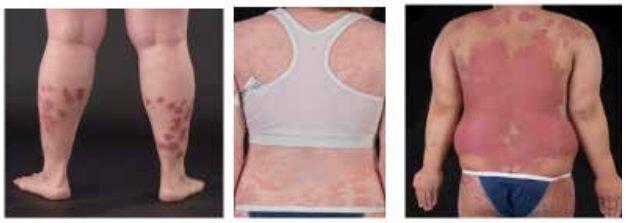
The BSA measure, introduced by the National Psoriasis Foundation, is a global impression rather than an exact calculation. Mild psoriasis is characterized by less than 3% involvement of the total body; severe psoriasis is said to encompass more than 10% of the body. However, the BSA measure has limitations as it does not consider the nature of the lesions themselves. A patient with palmar-plantar psoriasis may have severe disease affecting their ability to function, but the BSA could be only 2% (due to the focused location of the lesions) and thus may be characterized by some clinicians as mild disease.

The Physician Global Assessment (PGA) scale goes from 0 (clear) to 6 (severe). It is based on the coloration, thickness, and amount of scaling of the lesions. This severity rating system may also be more intuitive than the PASI because it is based on binary (0 or 1) measures and therefore may be more practice-friendly. Clinical trials often utilize PGA measures as a complement to PASI. One disadvantage of PGA measures is the lack of consideration about the BSA involved or the location of the lesions.[24]

Suggestions have also been made regarding the potential combination of rating scales (e.g., PASI × BSA) in an effort to improve the correlation between the score and symptom severity and extent (Figure 1). Due to lack of consensus on defining patient severity, a challenge for providers and payers is defining prior authorization criteria as well as defining outcomes to determine efficacy in patient management.

Another assessment involves PROs. For example, the DLQI, a questionnaire involving 10 domains, can result in a score from 0-30. Utilization of the DLQI can contribute to the overall holistic picture of the patient but is also rarely used in the office setting.

Figure 1. Putting PASI, and BSA Side by Side



Mild to moderate	Moderate	Severe
PASI: 4.2	PASI: 10.8	PASI: 18.4
PGA: 2-3	PGA: 2-3	PGA: 3-4
BSA: 4%	BSA: 18%	BSA: 32%
BSA×PGA: 4×3=12	BSA×PGA: 18×2=36	BSA×PGA: 32×4=128

Source: Kristin Callis Duffin, MD, MS.
BSA = body surface area; PASI = Psoriasis Area and Severity Index; PGA = Physician Global Assessment.

The underlying problem is that, without a consensus measure of the severity of psoriatic lesions, prescribers, payers, and researchers are challenged to accurately gauge the real-world effect of an intervention.

Payer Perspectives. Some payers have incorporated BSA measures into their PA criteria. For example, physicians may need to report a patient's BSA of 10% or more in order to receive biologic therapies. The subjective nature of severity assessment compounds the challenges of consistently defining treatment failure, adding time and potentially resources to the coverage determination process. As a result, payers often implement step therapy utilization management strategies for psoriasis, which require fewer administrative resources and lower barriers to access.

In 2016, the National Psoriasis Foundation introduced its "Treat to Target" strategy,[25] which emphasizes the setting of a specific target—to attain a BSA of ≤ 1% after 3 months of therapy—in patient treatment. An acceptable response was determined (using a Delphi process involving 25 dermatology experts) to be either a BSA ≤ 3% after 3 months of treatment or BSA improvement of ≥ 75% from baseline over that same time frame. If this is attained, evaluation every 6 months is suggested. The target response at every maintenance evaluation is a BSA ≤ 1%. Summit attendees offered that this may serve as the foundation for the first pay-for-performance outcomes measure in psoriasis.

Patient Expectation and Satisfaction. Treatment plans must also consider patients' definitions of success. Outside of complete resolution, each patient's interpretation of successful treatment may vary; therefore, it is important to engage patients early in treatment decisions to understand their expectations.

Innovation Outpaces Treatment Guidelines

Numerous medications were approved by the FDA in recent years to treat psoriasis (Table 1). They target several mechanisms along the inflammation pathway including PDE-4 inhibitors and interleukin inhibitors.

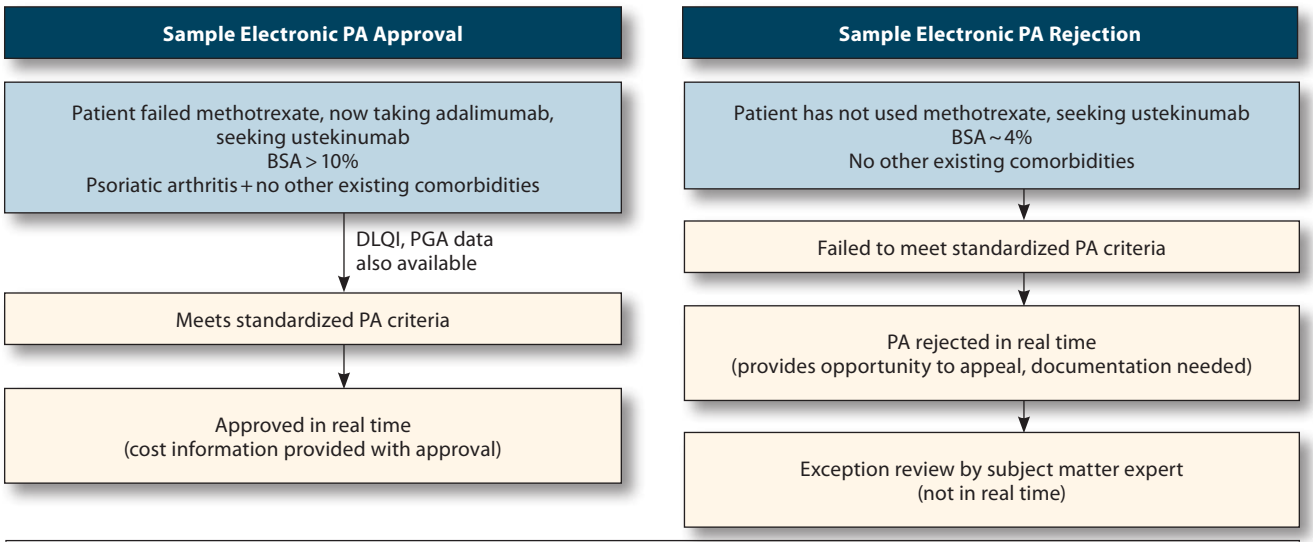
Up-to-date treatment algorithms are lacking, and without treatment goals and pathways, clinicians and patients have limited well-defined targets during the treatment course. The result is substantial variability in treatment expectation and quality of care. Although head-to-head data for some medications are being released, additional information on the comparative efficacy of biologics and traditional systemic agents is needed.

One significant consideration of appropriate reporting of improvement has resulted from new therapies raising the bar in defining response to treatment. Although a 75% gain in the PASI score has been used as a primary outcome in clinical trials, it is possible for most patients taking interleukin-17 or -23 inhibitors to achieve improvements of 90%, or even complete clearance. This also raises the possibility of achieving remission of symptoms. However, understanding the incremental value of achieving a PASI 75 versus PASI 90 or PASI 90 versus PASI 100 (including understanding the value of incremental psoriasis improvement on comorbid conditions) could be an important determinant in prescribing for individual patients and for populations.

Another way to understand the likelihood of reaching treatment goals that was reviewed by participants is the number-needed-to-treat (NNT) analysis (Table 2). This approach can help add clarity to formulary decision making and guide the consideration of comparative effectiveness.

Real-world evidence will contribute to an understanding of the side effect risks beyond the clinical trial setting. Currently, real-world evidence does not exist uniformly for clinical efficacy, safety, adherence, or risk of comorbid conditions for psoriasis. For the most recently approved biologics and those in the pipeline, this may take years to develop and publish.

Figure 2. Simplified Algorithm for Potential Electronic PA to Evaluate a Nonpreferred Drug Choice in Psoriasis



BSA = body surface area; DLQI = Dermatology Life Quality Index; PA = prior authorization; PGA = Physician's Global Assessment.

Adherence and Drug Survival. Drug survival,[26] or the duration a medication is taken by populations according to its prescribed regimen, is heavily influenced by the appearance or resolution of side effects (and their severity), a decrease in drug effectiveness, or simply a dropoff in patient adherence (idiopathic or related to cost-sharing issues), according to the clinicians attending the Summit.

One factor influencing drug survival is the use of higher-than-approved dosages of biologics, which may be the result of dosage escalation due to waning drug effectiveness or patient tolerance (e.g., appearance of antidrug antibodies). A challenge noted by payers was the inability to understand if dosage escalation is the result of lack of treatment efficacy or an increase in disease severity, making therapy approval a challenge, as this may also be an indication that a change in therapy may be warranted.

Evidence-Based Treatment Algorithm Based on Comorbid Considerations. An algorithm published in October 2017 suggests evidence-based recommendations for first-line biologic therapies in patients with psoriasis and distinct comorbid conditions or risk factors (Table 3).[27] If it is validated and gains acceptance, it may be a helpful tool in assisting clinicians to consider comorbidity when prescribing.

The 2017 approval of guselkumab and the rapid progress of other investigational interleukin-23 inhibitors through the pipeline suggests that published guidelines will require frequent updates to remain relevant.

Improving Patient Outcomes, Streamlining Prior Authorization Criteria and Processes

Summit participants formed workgroups to capture the principal challenges, opportunities, and potential solutions to managing psoriasis from a patient care perspective. Table 4 represents a summary of the reports from the 3 workgroups. Some important concepts are highlighted below.

Medication Therapy Management (MTM). Several participants asserted that medication therapy management MTM at the pharmacy level should be leveraged to help improve patient education and generate data. Specialty pharmacies often contact patients concerning their adherence and health status. This is an opportunity for a conversation with the patient regarding symptoms (progression or improvement), comorbid status, adherence, cost-sharing burden, and drug information. A specialty MTM program sponsored by the employer or the health plan must be more than an activity to comply with a contract. It is an opportunity to engage patients

Table 1. Specialty Medications Approved to Treat Plaque Psoriasis

Nonproprietary Name	Brand Name	Year Approved	Drug Class	Comments
Etanercept	Enbrel	1998	TNF-alpha inhibitor (FC fusion protein)	Only 50% of patients reach a PASI 75 response after 12 weeks, but also very effective for psoriatic arthritis; biosimilar approved in 2016 but not yet available
Infliximab	Remicade	1998	TNF-alpha inhibitor	IV infusion, challenge to route of administration; 80% reach PASI 75 by week 10; loses effectiveness after 1 year; administered with methotrexate; 2 biosimilars now available (Inflectra and Renflexis)
Adalimumab	Humira	2002	TNF-alpha inhibitor	Most commonly prescribed; 68% reach PASI 75 at week 16; also effective in psoriatic arthritis (has widest range of indications as well); one of the better durations of effect for the biologic category
Apremilast	Otezla	2014	PDE-4 inhibitor	Oral medication; approximately 30% reach PASI 75 at week 12; may be most useful in patients with mild to moderate symptoms
Ustekinumab	Stelara	2009	IL-12/23 inhibitor	Excellent duration of effect (5 year); 67% reach PASI 75 by week 16; excellent safety profile, but weight-based dosing may be disadvantage from payer perspective (but not physician perspective)
Secukinumab	Cosentyx	2015	IL-17A inhibitor	80% reach PASI 75 by week 12; 40% reach PASI 100. Head-to-head evidence vs. Stelara and Enbrel. Rapid improvement (in as little as 2 weeks). Injection site reactions common
Ixekizumab	Taltz	2016	IL-17A inhibitor	50% reached PASI 100 by week 16. Injection site reactions common. Do not give in patients with inflammatory bowel disease
Brodalumab	Siliq	2017	IL-17 receptor A inhibitor	37% reached PASI 100 after 1 year. 4 suicides in clinical trials (REMS program to address); only biologic that requires use of other available therapies first
Guselkumab	Tremfya	2017	IL-23 inhibitor	75% received PASI 90/100 scores; good safety profile

IL = interleukin; IV = intravenous; PASI = Psoriasis Area and Severity Index; PDE-4 = phosphodiesterase 4; REMS = Risk Evaluation and Mitigation Strategy; TNF = tumor necrosis factor.

multiple times in ways that facilitate positive outcomes using motivational interviewing techniques and patient segmentation. During this MTM contact, DLQI data can be collected at regular points in time, enhancing the overall clinical picture. Automatic enrollment would be triggered by the provider's prescription for a psoriasis specialty medication. One noted caveat was that this type of enhanced MTM function would have to be coordinated if a payer uses multiple specialty pharmacies, but Summit participants supported this approach for enhanced patient engagement.

Implications for Coverage Determinations. In terms of clinical policy making, well-accepted treatment guidelines are important in the development of PA criteria. The lack of updated clinical protocols in psoriasis can be problematic for payers, with implications for physician practices and patients.

Documentation requirements for psoriasis treatment authorizations could become lengthy and complicated if they consider comorbid conditions/risk factors, effectiveness in resolving dermatologic symptoms, and drug survival. The participants were concerned that increasing the complexity of authorization criteria based on comorbid conditions could result in additional documentation and time requirements from physicians' offices thus necessitating greater education and/or personnel to interpret the criteria and raising potential issues in provider relations. Differing documentation requirements among several payers in one geographic area often add to the burden on administrative resources and treatment delays.

Real-time interactions between physicians' offices and payers are available in some practices today. Based on the available electronic PA (ePA) infrastructure, some managed care organizations can adjudicate approvals while the patient is in the office. Optimally, documentation required for an ePA should be reasonable (i.e., require no more 6 clicks to complete). The Summit participants acknowledged that real-time authorization would not be practical if documentation includes physician attestation for the need for a particular drug as it is not objective nor includes measurable parameters for documentation.

Table 2. NNT to Achieve PASI Improvements at Primary End Point

Drug	NNT for PASI 75	NNT for PASI 90	NNT for PASI 100	Comment
Apremilast	3.6	–	–	ESTEEM 129
Methotrexate	3.2	5.6	25.0	METOP30
Etanercept	2.2	4.8	23.3	50 mg BIW
Adalimumab	1.6	2.3	5.3	40 mg EOW
Ustekinumab	1.6	2.9	9.2	90 mg
Infliximab	1.4	2.2	4.1	5 mg/kg IV
Brodalumab	1.3	1.5	2.7	210 mg
Secukinumab	1.3	1.7	3.6	300 mg
Guselkumab	1.2	1.4	2.6	VOYAGE 131
Ixekizumab	1.1	1.4	2.4	Uncover 232

Note: Highlighting indicates the lowest NNT for each PASI improvement.
Sources: Craig Leonardi, MD, St. Louis, MO; U.S. FDA Package Inserts or Phase 3 Trials; NNT Calculator: http://clincalc.com/Stats/NNT.aspx?example.
BIW = twice weekly; EOW = every other week; IV = intravenous; NNT = number needed to treat; PASI = Psoriasis Area and Severity Index.

Real-time authorization could also allow patients to receive information on their new drug from a nurse or educator before leaving the office instead of through a separate interaction that would occur 24-72 hours later, after the conventional PA is received.

The Summit workgroup developed a simplified flowchart through which justification of the request for a nonpreferred pharmaceutical might be approved in real time (Figure 2). They noted that some representation of drug cost information in the electronic medical record would also be beneficial in informing the physician and patient of the cost of the recommended choice of treatment; this would include patient cost-sharing based on his or her payer/plan. It was acknowledged that published price wholesale acquisition cost of medications is not reflective of the true pricing provided to payers, and the participants felt that providers need to have some sort of relevant cost data regarding treatment choices.

Enhanced Role of AMCP. AMCP can serve as a respected source of information for providers and payers. Webinars and continuing education programs with input from AMCP can be a source of useful drug information to address relative efficacy, risks, and costs—in particular, what sets these biologic medications apart from conventional psoriasis therapies.

Table 3. An Evidence-Based Algorithm on Biologic Therapy for Patients with Psoriasis and Comorbid Conditions[a,b]

Patients with psoriasis and psoriatic arthritis
1. Adalimumab, etanercept, and infliximab
2. IL-17 inhibitors
3. Ustekinumab (esp, if PsO is severe and PsA is mild)
Patients with psoriasis and multiple sclerosis
1. Ustekinumab (an IL-12/23 inhibitor)
2. IL-17 inhibitors
3. *Avoid all TNF inhibitors*
Patients with psoriasis and CHF
1. Ustekinumab
2. IL-17 inhibitors
3. *Avoid all TNF inhibitors in NYHA class 3 or 4 CHF and use with caution in NYHA class 1 or 2 CHF*
Patients with psoriasis and IBD
1. Adalimumab, infliximab, ustekinumab
2. Etanercept
3. Use secukinumab and ixekizumab cautiously in patients with IBD. Avoid brodalimumab in patients with Crohn's disease
Patients with psoriasis and hepatitis B
1. Ustekinumab
2. IL-17 inhibitors
3. TNF inhibitors

[a]*This algorithm is based on clinical data only and does not factor in cost or rebates (discussed elsewhere).*
[b]*This guideline was produced before the availability of IL-23 inhibitors.*
CHF = congestive heart failure; IBD = inflammatory bowel disease; IL = interleukin; NYHA = New York Heart Association; TNF = tumor necrosis factor.
Source: Amin M, No DJ, Egeberg A, Wu JJ. Choosing first-line biologic treatment for moderate-to-severe psoriasis: what does the evidence say? Am J Clin Dermatol. 2018 Feb;19(1):1-13.

Cost Transparency. The cost of biologic (and biosimilar) medications can be better managed with greater net cost transparency by the payer and awareness by the prescriber and the patient. Cost transparency has not yet been achieved consistently on any level: between doctors and plans, between members and plans, between corporate purchasers and plans, and even between patients and doctors. Yet, clinicians would be in a better position to prescribe more cost efficiently if they were provided information about members' cost sharing and plans' net costs for these products.

Furthermore, patients in high-deductible health plans may have to pay 100% of the cost of specialty pharmaceuticals before insurance coverage. Cost transparency, including a confirmation from the patient on whether

Table 4. Challenges, Opportunities, and Solutions in PA Criteria and Defining Outcomes

Challenge	Opportunity	Potential Solutions and Comments
Lack of accepted treatment algorithms/guidelines Patient variability in presentation and response	Need frequently updated, well-accepted guidelines to elucidate the effects of therapy on psoriasis (and its subtypes) and its comorbidities, offer an individualized protocol, and define the appropriate duration of a drug trial Assimilate payer coverage concepts into new guidelines, which may streamline incorporation into medical/pharmacy policies after acceptance	Professional societies should take up the challenge, which may lay the groundwork for consistent, appropriate PA criteria (beyond physician attestation) for use of first- or second-line biologics Include payer/population management considerations on guideline creation committees
Lack of objective, standardized, clinical practice markers of severity and measures of response	Consensus decision making on outcomes markers (describing a meaningful response) that are easy to use in practice but are suitably descriptive of patient presentation and therapeutic progress	This should consider not only objective markers but PROs (like the DLQI) to capture a more comprehensive clinical picture of the burden of disease and its effect on the patient at home or at school/work and measure improvement with treatment
Affordability of drugs and effect on access: patients	Creating medical and pharmacy policies that incentivize patients to use the most cost-effective drugs	Biosimilars must be ≥ 20% less (by net cost) than reference products to offer significant value
Affordability of drugs: payers	Use of standards (e.g., NNT) for determining the value of these agents Narrowing drug choices within each therapeutic category	An ICER or NNT approach may be a useful foundation; the solution should also consider patient cost sharing issues (e.g., if a patient fails a preferred agent, their cost sharing for a subsequent agent could be limited)
Limited awareness of drug costs by prescribers/patients	Education of prescribers at the time of the office visit (i.e., point of prescribing)	Interface of cost information (e.g., First DataBank) with EMR to illustrate the relative cost of medications, based on WAC and considering patient cost sharing based on plan policies Better real-time information for patients regarding their out-of-pocket costs (long-term and short-term) with the use of specific therapies; this, too, can be reflected in the e-prescribing modules of the EMR
Coordination of PA and lack of documentation for the PA	Approval of PA during the time of the visit Identification of a set of core PA criteria, acknowledged across plans, focusing on the use of drugs with different MOAs, the patient's QoL, and cost effectiveness Increased use of specialized reviewers/clinical experts to adjudicate appeals and exceptions	Implementation of real-time electronic PA approvals; include payer criteria as part of EMR (e.g., EPIC or other common systems); electronic PA infrastructure widely available but implemented in a minority of plans (though momentum is building for its wider use) A national payer organization (e.g., AMCP) can help to better inform clinicians and provider groups on the methodology and justification of the PA process and how it is used to ensure that patients are given access to appropriate medications
Alignment of incentives/contracting restrictions Contracts tied to other autoimmune disease states	Use of different contracting methods can change incentives in policy decisions and encourage the most effective therapies for psoriasis (e.g., indication-based contracting) Pay-for-performance incentives for providers Value-based contracting based on adherence, outcomes	The use of indication or MOA-based contracting or value-based approaches can emphasize the advantages of evidence-based (e.g., head-to-head) outcomes and begin to steer away from the exclusionary nature of common "1 of 1" or "1 of 2" contracting approaches. However, a consensus on suitable outcomes (or disease improvement) measures is needed
Lack of head-to-head studies on eEfficacy, safety, and effect on comorbidities	Useful head-to-head psoriasis treatment studies are being published, but their scope can be limited (e.g., not IL-17 vs. IL-23) and based on symptom efficacy, not comorbid risk factors and/or health economics	Head-to-head studies are contributing mounting evidence that the IL class of agents has substantially greater potential for achieving PASI 90 and PASI 100 improvement compared with anti-TNFs. Additional head-to-head investigations will be needed to determine whether any IL-17 or IL-23 agents offer comparative effectiveness by disease severity or whether the IL class has different effects on comorbid risk factors than other psoriasis therapies

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Table 4. Challenges, Opportunities, and Solutions in PA Criteria and Defining Outcomes *(continued)*

Education regarding psoriasis comorbidities and patient complexity	Creating a framework for providers (beyond dermatologists and affected specialists) to ingrain the importance of comorbidities into psoriasis treatment decision Access to specialists must be addressed in provider networks; this may be a problem not only for narrow plan networks but for geographic distribution of specialists	For providers, a pay-for-performance system may be designed based on new quality (process and outcome) measures to encourage the screening of patients with psoriasis for other risk factors and common comorbidities/outcomes (e.g., ED admission for cardiovascular events or related to glycemic control) For patients, a specialty MTM approach may assist in risk factor assessment and education
Access to specialists	PCP reluctance to prescribe (and PA requirement that only specialists prescribe) biologics	Greater use of telemedicine to gain access to specialists (not yet covered by all plans in all geographic locations that could benefit most); need more consistent funding mechanisms to expand telemedicine use
Value of incremental benefits (e.g., PASI 90 vs. PASI 100)/ understanding patient expectations	Better use of DLQI, tied to clinical ratings Opportunity to discuss cost of medications vs. incremental benefit	Better understanding of which outcomes matter to patients Educational efforts to raise provider awareness of analyses like NNT

DLQI = Dermatology Life Quality Index; ED = emergency department; EMR = electronic medical record; ICER = Institute for Clinical and Economic Review; IL = interleukin; MOA = mechanism of action; MTM = medication therapy management; NNT = number needed to treat; PA = prior authorization; PASI = Psoriasis Area and Severity Index; PCP = primary care physician; PRO = patient-reported outcome; QoL = quality of life; TNF = tumor necrosis factor; WAC = wholesale acquisition cost.

he or she understands the costs, during the physicians' office visit with the patient can increase the probability that the patient will adhere to the prescribed regimen.

Providers can benefit from a payer perspective on costs (a) by familiarizing clinicians with payers' decision-making processes and the factors influencing coverage choices (including the costs of therapies and patient cost-sharing responsibilities) and (b) by obtaining payer representation and input on the development of clinical guidelines. The former can be achieved through several methods, including live and prerecorded webinars that could qualify for continuing education credits. These webinars may also address physicians' questions about the most efficient way to obtain needed medications for their patients. The latter may also offer the benefit of facilitating the incorporation of clinical guidelines into individual health plan coverage policies. Summit participants agreed that the payers' voice is currently lacking in the development of clinical guidelines by professional societies. Payers represented individually (i.e., different payer types) or through a national association could offer a valuable viewpoint in the guideline development process.

AMCP can also support education regarding areas of need through its currently available national educational conferences and print and web-based publications.

Stakeholder Aspirations for Specialty Pharmacy Management

Payers. A panel discussion highlighted the implications of rising specialty pharmacy costs on payers and pharmacy benefit managers (PBMs) and on how they provide access to affordable benefits.

Payers are seeking assistance from clinicians, pharmaceutical manufacturers, and patients in managing the prescription drug benefit, the cost of which continues to rise. They are seeking to place the most cost-effective drugs on their formularies but also offer clinicians treatment options (without the need for bureaucratic barriers to obtain the right drug for their patients).

To support appropriate utilization, payers and PBMs recommend that manufacturers focus on the cost of the drug rather than on value-added services and direct-to-consumer advertising. Value-added services should be directed to patients rather than to payers. For example, patient education provided by the manufacturer will not generally be utilized by the health plan or insurer; this type of value-added content might be better given directly to patients.

Copay coupons are not helpful for payers and PBMs when the drug is not in a preferred position. Several do not accept member copay incentives for specialty drugs. If the medication has been approved through PA, the

Table 5. Payer Management Challenges, Opportunities, and Solutions

Challenge	Opportunity	Potential Solutions and Comments
Overall high cost of category Investing in bBiologic therapies with short plan-membership horizons	Incorporation of biosimilars Rapid onset of effect and symptom alleviation/potential clearance of symptoms (remission) Drug cost transparency	Benefit design strategies incorporating preferred and nonpreferred specialty tiers; exclusions and step edits (depending on price savings expected with biosimilars) Patients often see PASI 75/90 improvements within 16 weeks; anti-TNF and IL agent effects on comorbidities may require longer periods to measure effects
Biosimilar launches delayed	Biosimilars can disrupt current contracts, allowing for consideration of other contracting methods Lower potential costs with greater competition	Predicting biosimilar launch dates can be frustrating; anticipated launches may persuade payers to not make formulary changes, which may then ease biosimilar transitions (i.e., not encouraging the use of other biologics because of impending biosimilar availability)
High-deductible health plan designs	Educate prescribers on costs of therapy and cost sharing requirements of patients	Utilize relative cost symbols in EMR; provide cost information to members Provide clearer policy information to members as to what medical/pharmaceutical benefit interventions may count/not count toward the deductible and may depend on how the benefit is designed Emphasize that use of copay coupons may not count toward deductibles
Current market basket and rebate contracts, with rebates at risk across indications (psoriasis-only indications for newest biologics)	Indication-based or MOA-based contracting Approval of biosimilars Drug cost transparency	The future will be biosimilars and "me-too" drug approvals, which can result in portfolio contracting opportunities Work with pharmaceutical manufacturers to redefine the market basket by anti-TNF, and IL categories New indications are expected in the future, which will make formulary coverage and preference for these new biologics more palatable Create a white paper describing the importance of net costs, including the effect of exclusionary contracts/rebates, and why modifying coverage of existing medications can be problematic (e.g., considering loss of rebates)

EMR = electronic medical record; IL = interleukin; MOA = mechanism of action; PASI = Psoriasis Area and Severity Index; TNF = tumor necrosis factor.

specialty pharmacy can (and often does) direct patients to patient assistance programs.

Payers are requesting information from researchers, pharmaceutical manufacturers, and the provider community that can facilitate their ability to identify and address treatment failures, without the administrative challenges that are associated with tracking outcomes.

They would like clinicians to be more cognizant of the costs of these medications and consider this in treatment changes before selecting treatments with biologic drugs. They also emphasize that clinicians should try to use the plan or PBM's preferred drugs first, to support evidence-based care decision making and minimize patient cost sharing.

Employers. In general, self-funded employers are not interested in intensively evaluating individual drug costs. They want more control over how health care dollars are spent, but they would rather rely on broader approaches to achieve their priorities. For example, employers want to utilize a value-based formulary, based on firm evidence, to help them control costs but not be involved in the evidence evaluation of which drugs are covered on the formulary.

A value-based formulary requires an ongoing evaluation of clinical studies and new evidence of benefit and risk for medications. Clinical guidelines developed by professional societies are an important component of the evidence review, and up-to-date unbiased guidelines are important in the maintenance of a value-based formulary. Finally, many pharmacy and therapeutics committees or medical benefit policy committees consider comparative-effectiveness research and relative costs of current formulary options.

Some of the challenges to this value-based formulary approach include:

- More comparative-effectiveness studies are needed.
- Outcomes measures used in clinical studies are sometimes surrogates for outcomes.

- Guidelines are not updated frequently enough to reflect changes in technology and practice.
- There is a lack of cost transparency.
- Disruptive new technologies for rare diseases (e.g., CAR-T gene therapy) potentially carry costs that will dwarf those of current biologic medications.
- Current preferred products are part of long-standing contracts, which do not allow for the addition of newer products that are potentially more efficacious or safer.

Payer Management Considerations in Psoriasis

Summit participants formed workgroups to capture the principal challenges, opportunities, and potential solutions to managing psoriasis from a payer perspective. Table 5 represents a summary of the reports from the 3 workgroups.

Biosimilars. Biosimilars may be a category-disrupting influence that amplify the opportunity for preferred/nonpreferred tiering of specialty products and may lead to reconsideration of the merits of conventional rebate contracts. However, only 2 biosimilars are currently marketed in the autoimmune class (for the same reference product—infliximab).[28] Therefore, expectations for the category must be tempered with the realization that biosimilar launches for the most utilized biologic agents—adalimumab and etanercept—may not occur in the near future. Although it may be tempting to payers to encourage that patients be treated with adalimumab in the hope of easing wholesale transition to a less-expensive biosimilar, this may not occur until its relevant patents expire in 2023.[9]

A Psoriasis-Specific Opportunity. The average duration of plan membership can be brief, particularly in unstable markets or exchanges where consumers may see significant changes in plan premiums and/or benefits from year to year. Members may need to switch plans or discontinue coverage based on other economic factors and employment choices. Payers may be concerned that investing high dollar amounts in specialty treatments may not result in population-wide improvements before members leave their plan. This may be less of a concern in psoriasis given that biologic treatment often results in significant improvement in dermatologic symptoms within 16 weeks. However, the effect of treatment on existing or potential comorbidities may not be seen in such a short period. Although these immunomodulators have been shown to improve comorbid disease in patients with psoriasis, payers should broaden their perspective to that of population-wide (or community-wide) care.

Summary

In the treatment of moderate to severe plaque psoriasis, specialty pharmaceuticals, especially biologics, are an important treatment choice in helping patients obtain the best outcome possible. The recent influx of new biologics and biosimilars has resulted in expanded options in terms of mechanism of action, effectiveness, and safety. Owing to patent litigation, some of the most useful biosimilars approved to treat psoriasis may not be available for some time (i.e., beyond 2018).

Our ability to optimize treatment for individual patients and populations is still hindered in a basic way: a consensus by the dermatologic community is needed in determining the best method to consistently and practically measure symptom status and degree of skin improvement in the doctor's office. The description "moderate to severe" psoriasis does not correlate with today's measurement tools, and the value and ease of measuring incremental improvement using these or more advanced tools needs to be elucidated.

Psoriasis is not a benign disorder. The links between advanced psoriasis symptoms and serious comorbidities (e.g., cardiometabolic disease) have been proven. Patients with moderate to severe psoriasis are subject to depression and poor QoL in general. Yet these facts often do not influence coverage decision making (and general prescribing). The publication of clinical guidelines that directly address comorbidities and treatment's effect on comorbid risk factors will help incorporate these elements into clinical decision making.

Providers need greater transparency and education on the reasons behind managed care formulary choices and the process by which coverage decisions (including PA and step therapy criteria) are made. Professional organizations and societies can play a vital role in offering an opportunity for clinicians and payers to continue to discuss and develop optimal patient management approaches. These organizations can also provide information, education, and training to help clinicians understand the need for cost transparency for specialty pharmaceuticals and elucidate how pharmaceutical contracts influence coverage decisions. Cost transparency will help inform all stakeholders about the true expenditures and value of various products and classes of medications.

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The AMCP Market Insights Program

The AMCP Market Insights Program is a 1-day multidisciplinary program integrating AMCP members with key opinion leaders and practicing clinicians in the discussion regarding patient management of a disease state or condition. The focus of the program is to address the needs of AMCP members, such as disease and utilization management, in this issue. This program provides the sponsors the opportunity to provide education regarding current and pipeline treatments and understand AMCP members' approaches to category and disease management.

The AMCP Market Insights Program is a blinded market research program sponsored by AMCP corporate sponsors (who also remain blinded to the participants), allowing an unbiased and objective approach to the content and program. Future programs are identified through AMCP member and corporate sponsor interest.

Please contact Charlie Dragovich at cdragovich@amcp.org for additional information regarding future Market Insights programs.