Specialty Pharmacy Care and Cost Management Strategies for PSORIATIC DISEASE THERAPIES



Jointly provided by





This activity is supported by independent educational grants from Celgene Corporation, Lilly USA, Inc. and Novartis Pharmaceuticals.



## Learning Objectives



- Explain the pathophysiology and immunologic pathways of psoriatic disease
- Align psoriatic disease specialty drug treatment algorithms with evidence-based treatment recommendations
- Utilize care pathways as cost management and appropriate use tools in psoriatic disease
- Employ specialty pharmacy and disease management services for psoriatic disease patients



## Current Evidence-Based Recommendations for the Treatment of Psoriasis

Alan Menter, MD

Chief, Division of Dermatology Baylor University Medical Center

### Learning Objective

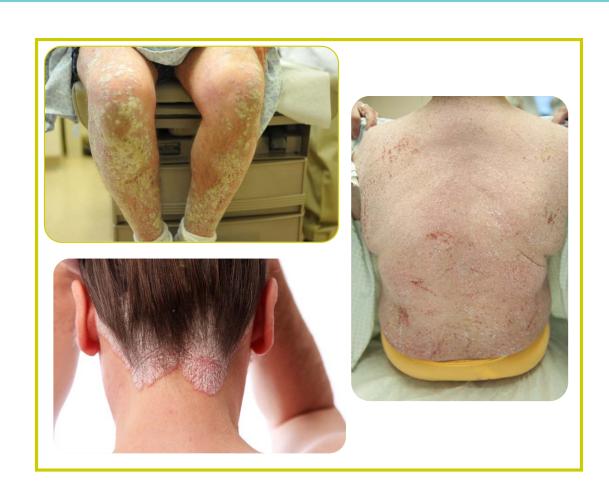


- Align psoriasis therapy with evidence-based treatment recommendations
- Understand the systemic nature of psoriasis with multiple associated comorbid conditions

# Chronic Plaque Psoriasis: A Multisystem Inflammatory Disease



- Chronic relapsing immune-mediated inflammatory disease
- Affects 2-3% of the US population
- Affects multiple areas of the body
- Up to 30% of patients with psoriasis develop psoriatic arthritis, usually 10-15 years after onset of psoriasis
- Accompanied by significant clinical, social, emotional, and economic burden
- Multiple associated comorbidities



# Plaque Psoriasis is the Most Common of the Five Recognized Clinical Variants



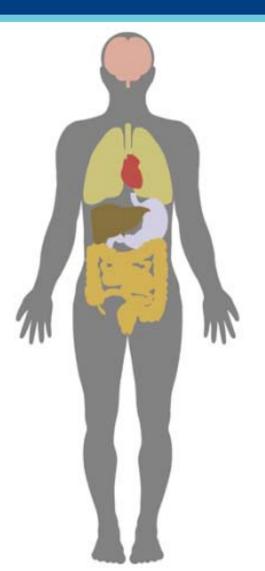
- Plaque: scaly, erythematous patches, papules, and plaques that are frequently pruritic; affects ~80% of patients
- Inverse/flexural: lesions are located in the skin folds
- Guttate: small papules (< 1cm) with fine scale
- **Erythrodermic:** erythema covering nearly the entire body surface area with varying degrees of scaling
- Pustular: clinically apparent pustules

#### **Severity of Plaque Psoriasis**



## Individuals with Psoriasis are At Risk of Developing Other Chronic Comorbid Conditions





**Depression/Anxiety** 

↑ risk of poor self-esteem, psychological stress, and anxiety due to their psoriasis

**Cardiovascular Disease** 

39% 个 risk of CV mortality

70% 个 risk of MI

56% 个 risk of MI

Obesity

346% ↑ risk (mild psoriasis) 123% ↑ risk (severe)

**Metabolic Syndrome** 

22% 个 risk (mild) 98% 个 risk (severe)

**Diabetes** 

14% ↑ risk (mild)

46% 个 risk (severe)

**Psoriatic Arthritis** 

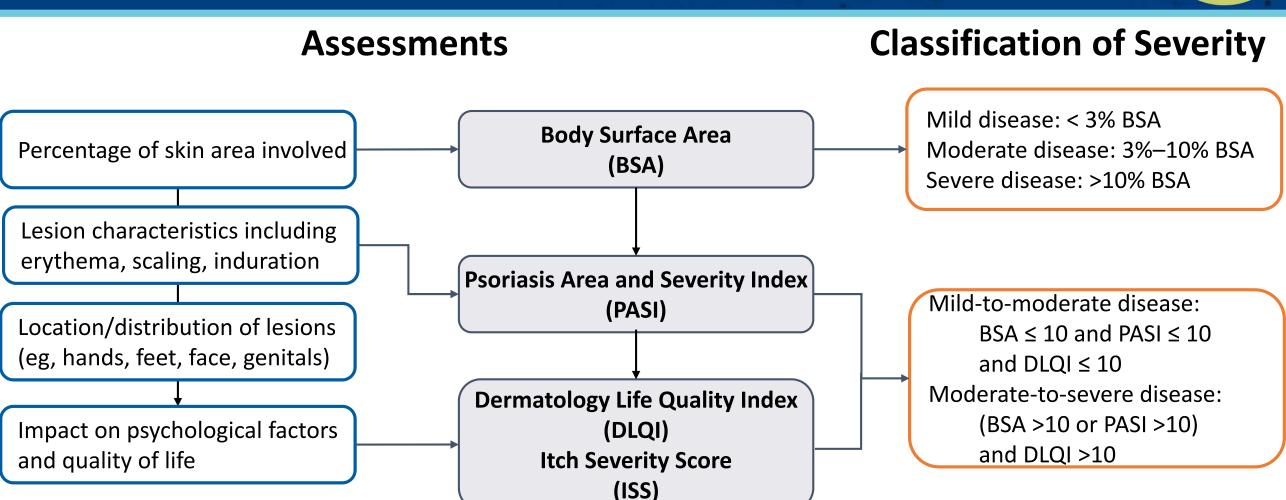
↑30 % of patients

10-15 years after onset of psoriasis

Elmets CA, Leonardi CL, Davis DMR, et al. *J Am Acad Dermatol*. 2019;80(4):1073-1113. Ni C, Chiu MW. *Clin Cosmetic Invest Dermatol*. 2014;7:119-32.

### Assessing Psoriasis Severity

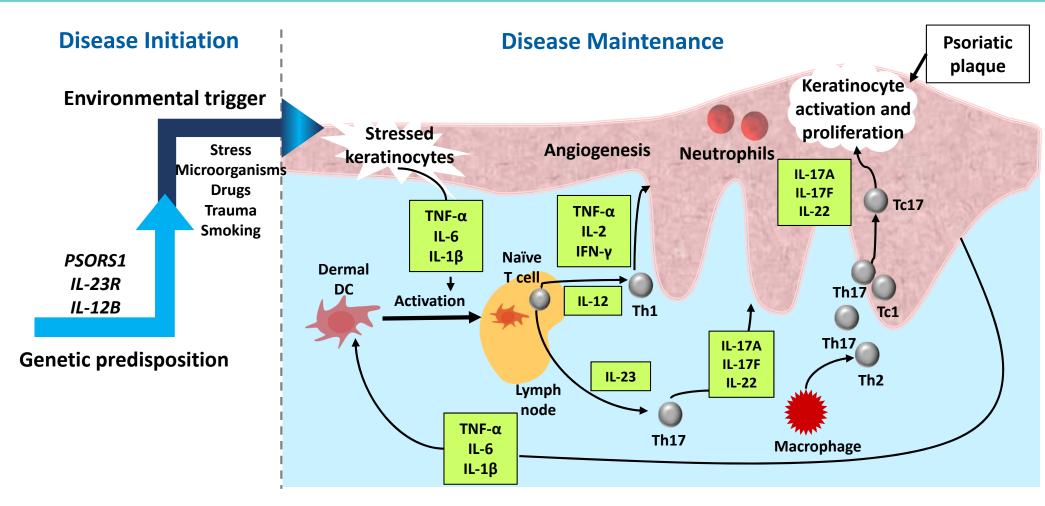




Armstrong AW, Robertson AD, Wu J, Schupp C, Lebwohl MG. *JAMA Dermatol*. 2013;149(10):1180-5.; Menter A, Gottlieb A, Feldman SR, et al. *J Am Acad Dermatol*. 2008;58(5):826-50.; Spuls PI, Lecluse LL, Poulsen ML, Bos JD, Stern RS, Nijsten T. *J Invest Dermatol*. 2010;130(4):933-43.; Both H, Essink-bot ML, Busschbach J, Nijsten T. *J Invest Dermatol*. 2007;127(12):2726-39.; Mrowietz U, Kragballe K, Reich K, et al. *Arch Dermatol Res*. 2011;303(1):1-10.; Majeski CJ, Johnson JA, Davison SN, Lauzon CJ. *Br J Dermatol*. 2007;156(4):667-73.

## Immunopathogenesis of Chronic Plaque Psoriasis





DC=dendritic cell; PSORS1=psoriasis susceptibility 1; IL=interleukin; TNF=tumor necrosis factor.

Gaspari AA, Tyring S. Dermatol Ther. 2015;28(4):179-93.; Nestle FO, Kaplan DH, Barker J. N Engl J Med. 2009;361(5):496-509.

# Therapeutic Agents Target Important Steps in the Pathophysiology of Psoriasis



- Several classes of biologic agents are available to target important steps in the pathophysiology of moderate-to-severe psoriasis
  - Anti-TNF-α
  - Anti-IL-12/23
  - Anti-IL-17
  - Anti-IL-23
  - PDE-4
- However, current data does not fully elucidate their ideal use, including
  - Matching patients with the most appropriate treatment
  - Ideal combinations and sequencing of agents

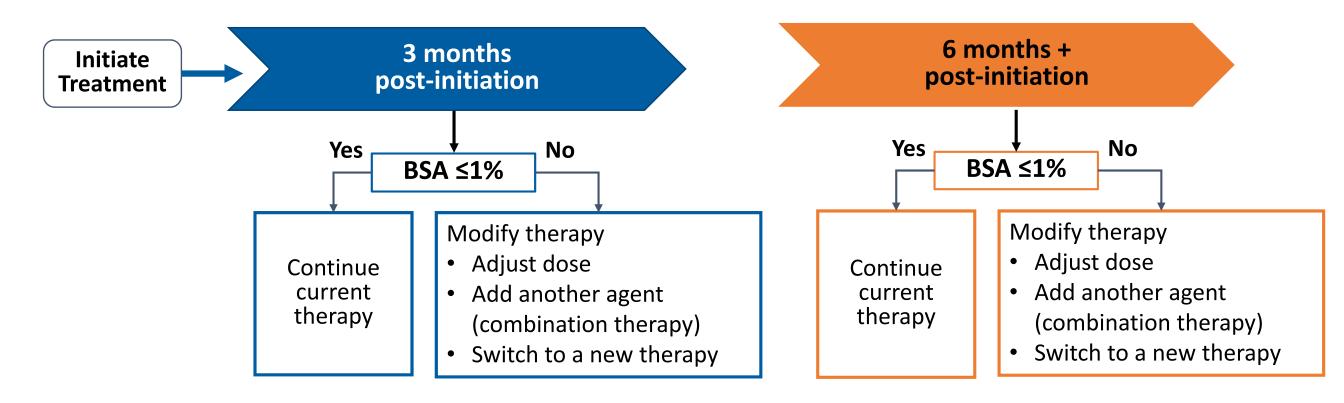
### Treatment Approach: Treat-to-Target





National Psoriasis Foundation Consensus Target Response: Reduce BSA to ≤1% three months after initiating treatment

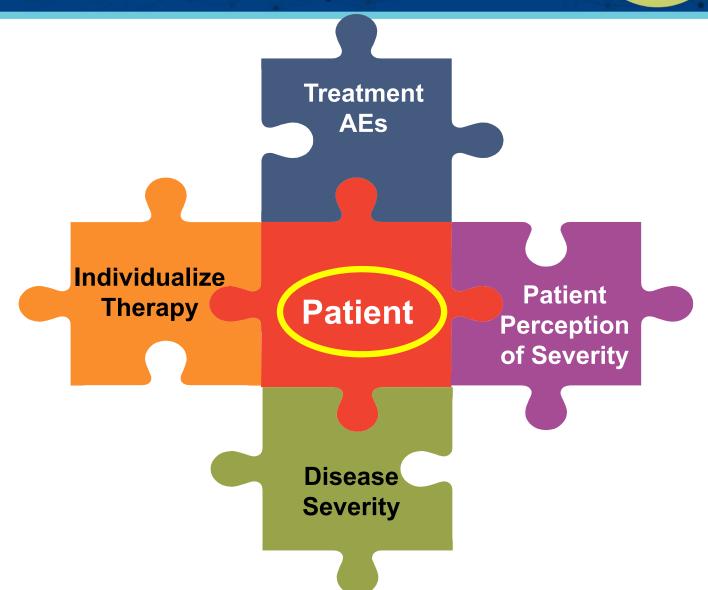




### Treatment of Psoriasis: Establish Individualized Treatment Goals

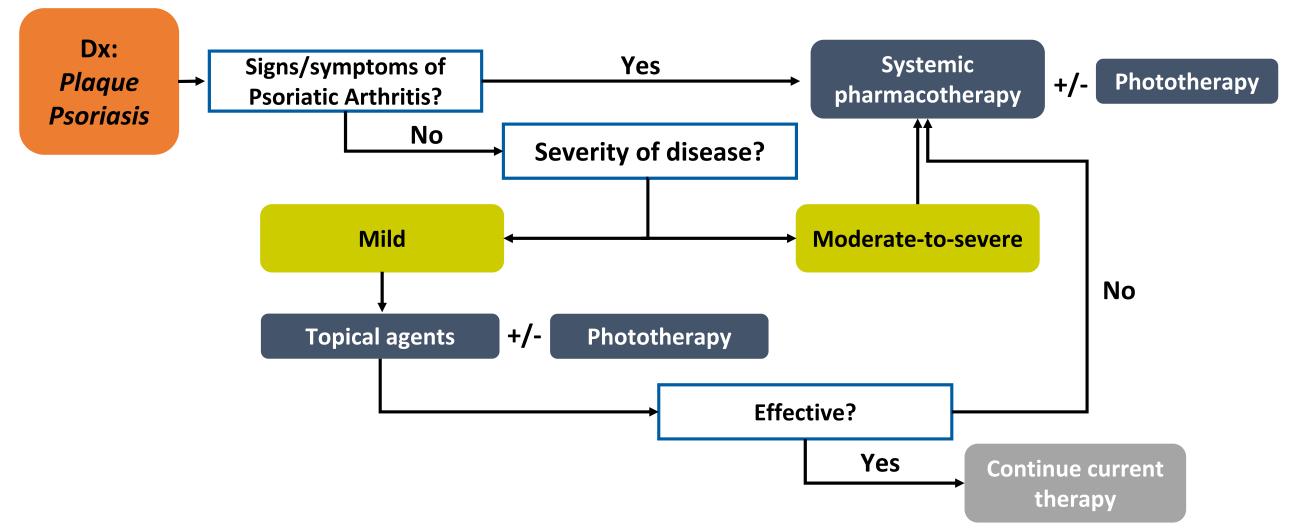


- Treatment goals<sup>1</sup>
  - Clear the skin
  - Minimize adverse events
  - Enhance patient quality of life
  - Address comorbidities
- Involve the patient in treatment decision making<sup>1,2</sup>
  - Consider patient preferences when selecting therapy



## Use Disease Severity to Guide Treatment Selection





Menter A, Gottlieb A, Feldman SR, et al. *J Am Acad Dermatol*. 2008;58(5):826-50.; Menter A, Korman NJ, Elmets CA, et al. *J Am Acad Dermatol*. 2009;60(4):643-59.; Menter A, Korman NJ, Elmets CA, et al. *J Am Acad Dermatol*. 2010;62(1):114-35.

## Biologics and Small Molecules Approved for the Treatment of Moderate-to-Severe Psoriasis



#### **Therapeutic Target**

TNF-α

IL-12/23

IL-17A Receptor

**IL-17A** 

**IL-23** 

PDE-4

**Adalimumab** 

Certolizumab

Pegol

**Ustekinumab** 

**Brodalumab** 

**Secukinumab** 

ccakiiiaiiiab

Guselkumab

**Apremilast** 

Ixekizumab

Tildrakizumab

Risankizumab

Etanercept

Golimumab

Infliximab

**Biosimilars** 

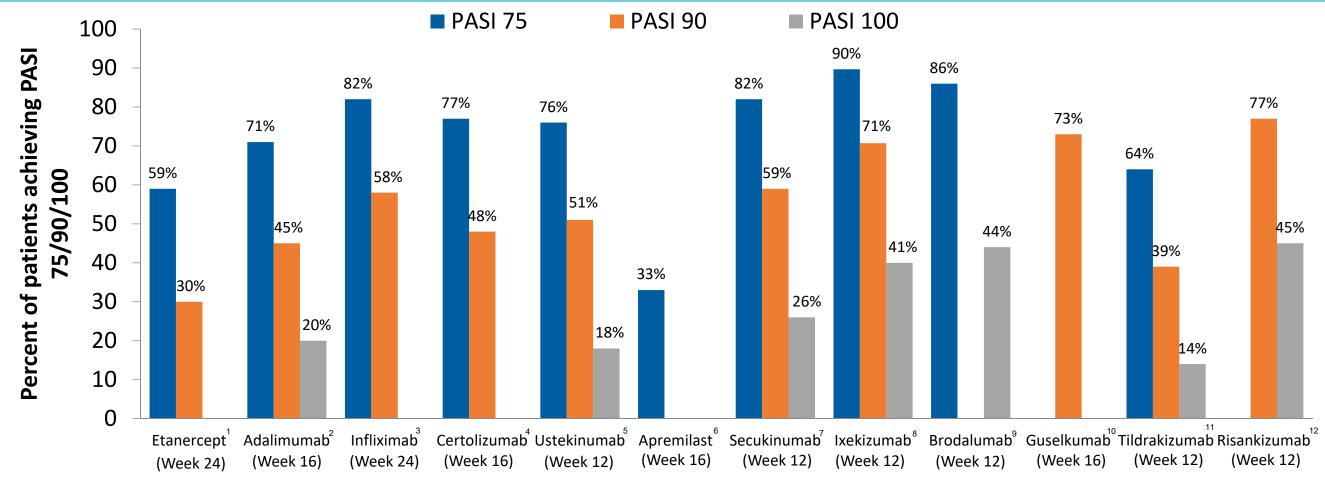
TNF=tumor necrosis factor; IL=interleukin; PDE-4=phosphodiesterase

Menter A, Strober BE, Kaplan DH, et al. J Am Acad Dermatol. 2019;80(4):1029-1072.

Treatment Comparison. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/treatment\_comparison\_chart\_2018.pdf. Accessed March 2019.

# Biologics Approved for Moderate-to Severe Plaque Psoriasis: PASI 75, 90, and 100 Scores





1. Leonardi CL, Powers JL, Matheson RT, et al. *N Engl J Med*. 2003;349(21):2014-22.; 2. Menter A, Tyring SK, Gordon K, et al. *J Am Acad Dermatol*. 2008;58(1):106-15.; 3. Reich K, Nestle FO, Papp K, et al. *Lancet*. 2005;366(9494):1367-74.; 4. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB, Inc; 2018; 5. Papp KA, Langley RG, Lebwohl M, et al. *Lancet*. 2008;371(9625):1675-84.; 6. Otezla (apremilast) [prescribing information]. Summit, NJ: Celgene Corp; 2014; 7. Langley RG, Elewski BE, Lebwohl M, et al. *N Engl J Med*. 2014;371(4):326-38.; 8. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; 2016; 9. Siliq (brodalumab) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals NA, LLC; 2017; 10. Tremfya (guselkumab) [prescribing information]. Cranberry, NJ: Sun Pharma; 2018; 12. Papp KA, Blauvelt A, Bukhalo M, et al. *N Engl J Med*. 2017;376(16):1551-1560.; 13. Menter A, Strober BE, Kaplan DH, et al. *J Am Acad Dermatol*. 2019;80(4):1029-1072.

## Biosimilars Approved in the US for the Treatment of Moderate-to-Severe Psoriasis



Biosimilar Product	Reference Product	Approval Date	Status
infliximab-dyyb/Inflectra	infliximab/Remicade	April 5, 2016	Commercially available
etanercept-szzs/Erelzi	etanercept/Enbrel	August 30, 2016	Not available
adalimumab-atto/Amjevita	adalimumab/Humira	September 23, 2016	Not available
infliximab-abda/Renflexis	infliximab/Remicade	April 21, 2017	Commercially available
adalimumab-adbm/Cyltezo	adalimumab/Humira	August 25, 2017	Not available
infliximab-qbtx/lxifi	infliximab/Remicade	December 13, 2017	Not available
adalimumab-adaz/Hyrimoz	adalimumab/Humira	October 31, 2018	Not available

- Biosimilars are successors to biologic agents that have lost patent exclusivity
- Not a simple generic, but highly similar to the reference product
- No clinically meaningful differences have been observed between the biosimilar and reference product in terms of the safety, purity, and potency
- Label reflects that of the reference product

Treatment Comparison. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/treatment\_comparison\_chart\_2018.pdf. Accessed March 2019.

## Updated Psoriasis Treatment Guidelines Now Available



#### Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention



Craig A, Elmets, MD (Co-Chair), \*Craig L, Leonardi, MD, \*Dawn Joel M, Gelfand, MD, MSCE, \*Jason Lichten, MD, \*Nehal N, Mehta, MD, MSCE, \*Cody Connor, MD, \*Kelly M, Cordoro, MD, \*Boni E, Elewski, MD, \*Ke Alice B, Gottlieb, MD, PhD, \*Daniel H, Kaplan, MD, PhD, \*Daniel k Rovahinsky, MD, \*M atthew Kselica, \*Neil, Korman, MD, PhD, \*Daniel k Rvoshinsky, MD, \*M Henry W, Lim, MD, \*Amy S, Paller, MD, \*Sylvia L, Parra, MD, \*Arnu L, Pathy, MB Reena Rupani, MD, \*Michael Siegel, PhD, \*Benjamin Soff, MD, MA, \*Bru Emily B, Wong, MD, \*Jashin J, Wu, MD, \*Vicliya Hariharan, PhD, \*and Ale Brimingbam, Alabama; St. Louis, Missouri; Rochester, Minnesota; Philaded Oregon; Belbesda, Maryland; Los Angeles and San Francisco, California, York, New York; Pitisburgh, Pennsylvania; San Diego, California; Dallas, To Massachusetts, Detroit, Michigan; Cheago, Illinois; Sumter, South Caro Oklaboma City, Oklaboma, Alaanta, Georgia; Farmington, Connecticut; Win Evas: Irvine, California; and Rosemont, Illinois.

Psoriasis is a chronic, inflammatory, multisystem disease that affects up to 3. guideline addresses important clinical questions that arise in psoriasis mar recommendations on the basis of available evidence. (I Am Acad Dermato

Key words: alcohoj, anxiety; cancer, cardiovascular disease; chronic obstrucinical guidelines for psoriasis, comorbidities; congestive heart failure; depraercitie dysfunction; guidelines; hyperlipidemia; hypertension; inflammatory metabolic syndrome; obesity; obstructive sleep apnea; psoriasis; psoriatic ard disease; sexual health; skin disease; smoking; ureitis; work productivity.

From the University of Alabama, Birminglaum<sup>2</sup>, Central Dematology, St. Louis<sup>2</sup>, Mayo Olini, Rocheater, University of Pennyalvania Pereiman School of Medicine, Philadelphia<sup>2</sup>, National Perorias Foundation, Portland<sup>2</sup>, National Heart Lung and Blood Institute, National Institutes of Health, Bethesda<sup>2</sup>; University of Southern California, Los Angeles<sup>2</sup>, Department of Dematology, University of California San Francisco School of Medicine<sup>2</sup>, Medical College of Wisconsin, Miswakee<sup>2</sup>: Department of Dematology, Leahn School of Medicine at Mr. Sinal, New York, University of Pietburgh<sup>2</sup>; University of California San Diego<sup>2</sup>, Baylor Scott and White, Dallach<sup>2</sup>; University Hospitals Gleveland Medical Central Control of Peroperation of Dematology, Henry Ford Hospital, Detroit<sup>2</sup>, Northwestern Dematology, Henry Ford Hospital, Detroit<sup>2</sup>, Northwestern University Ferberg School of Medicine, Chicago<sup>2</sup>; Dematology and Sinis Surgey, Sumetr<sup>2</sup>; Colorado Permanente Medical Group, Centennia<sup>3</sup>; University of Chaldhoran Health Sciences Center, Oklahoma City<sup>2</sup>; Emory University School of Medicine, Atlanta<sup>3</sup>; University of Connecticut, Famingoron<sup>2</sup>; Probly Medical Research, Waterloo<sup>2</sup>; San Antonio Uniformed Services Health Education Consortium, Jointéses San Antonio<sup>3</sup>; and American Academy of Dematology, Rosenont<sup>4</sup>.

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#### FROM THE ACADEMY

#### Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics

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Procises is a chronic, influrmanory multisystem disease that affects up to 3,2% of the US population. This guideline addresses important dirical questions that arise in procises management and care, providing recommendations based on the available evidence. The treatment of portacis with biologic agents will be reviewed, emplassing treatment recommendations and the role of the dermatologis in monitoring and educating patients regarding benefits as well as associated risks (J. Am Acad Dermat 2019;80:1097-72.)

Key words: biologic agents; clinical guidelines for psoriasis; dermatology, guidelines, monoclonal antibodies: psoriasis; skin disease.

he information presented here represents the authors disclosed relationship with industry during guideline development.

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Authors (listed alphabetically) with relevant conflicts with respect to this guideline are noted with an asterisk. In accordance with American Academy of

American Academy of Dermatology (AAD) strives to produce closical guidelines that reflect the best analysis evidence supplies between supplies and guidelines that reflect the best analysis evidence supplies with the produced with the judgment of expert criticates. Significant efforts are taken to maintaine the potentials for conflicts of interest for influence guideline content. The management of conflict of interest for this suitables complies with the Causard in Medical Speciality Societies' Code of interestation with Companies. Funding of guideline poduction by medical or planness results certained in president and medical politication of the production of the production of president or planness results of entities to produce a transition of the production of the production of the conflict of interest policy summary may be viewed at waves and cogs. The conflict of interest of the individual working group members are listed in that text of this guideline.

Reprints not available from the authors. Corresponding author Vidhja Harlharan, PhD, American Academy of Dermatology, 9500 West Bryn Mawr Ave. Rosemont. IL 60018. E-mail: vhanifuran@ad.org. Published online February 13, 2019.

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 The American Academy of Dermatology and National Psoriasis Foundation have released 2 joint guidelines for the management and treatment of psoriasis<sup>1,2</sup>

- One set addresses common comorbidities seen with psoriasis (e.g., PsA, CVD, metabolic syndrome, mental health conditions, IBD) and how their presence impacts psoriasis management<sup>1</sup>
- The other discusses the treatment of psoriasis using biologics<sup>2</sup>

1. Elmets CA, Leonardi CL, Davis DMR, et al. *J Am Acad Dermatol*. 2019;80(4):1073-1113. 2. Menter A, Strober BE, Kaplan DH, et al. *J Am Acad Dermatol*. 2019;80(4):1029-1072.

### Intended Use of the Revised Guidelines



- The revised guidelines are designed to:
  - Reinforce dermatologists' knowledge of psoriasis and how to treat it
  - Provide other health care providers a reference to use when caring for people with psoriasis
  - Provide health insurance companies up-to-date treatment information needed to design appropriate coverage policies for their members living with psoriasis
  - Provide patients with information that can help them improve their knowledge of psoriasis and how to work with their provider to achieve the best health outcome possible

## Guidance on the Use of Psoriasis Pharmacotherapy



- Mild-to-moderate psoriasis can be controlled with topical medications and/or phototherapy
- Biologics are more successful and have a higher benefit-to-risk ratio in the treatment of moderate-to-severe disease
- Biologics reviewed in the guidelines include:
  - Tumor necrosis factor alpha inhibitors (etanercept, infliximab, adalimumab, certolizumab pegol)
  - Interleukin (IL)-12/IL-23 inhibitors (ustekinumab)
  - IL-17 inhibitors (secukinumab, ixekizumab, brodalumab)
  - IL-23 inhibitors (guselkumab, tildrakizumab, risankizumab)

# Biologics and Small Molecules in Late Stage Development



Agent	Therapeutic Target (MOA) /Means of Administration	Status
BCD-085	<ul><li>IL-17 inhibitor</li><li>Self-injectable</li></ul>	Phase 3
BMS-986165	<ul><li>TYK2 kinase inhibitor</li><li>Oral</li></ul>	Phase 3
Bimekizumab	<ul><li>IL-17A and IL-17F inhibitor</li><li>Self-injectable</li></ul>	Phase 3
Piclidenoson	<ul><li>Adenosine A3 receptor inhibitor</li><li>Oral</li></ul>	Phase 3
LAS41008	<ul><li>Dimethyl fumarate (anti-inflammatory)</li><li>Oral</li></ul>	Phase 3
Mirikizumab	<ul><li>IL-23 inhibitor</li><li>Self-injection</li></ul>	Phase 3
Serlopitant	<ul><li>Neurokinin-1 receptor antagonist (anti-pruritic)</li><li>Oral</li></ul>	Phase 3

Drugs in the Pipeline for Psoriasis and Psoriatic Arthritis. National Psoriasis Foundation website. https://www.psoriasis.org/drug-pipeline. Accessed March 2019.

## Skin Disease Precedes Joint Involvement in 80-90% of Patients



### 3 in 10

Patients with Psoriasis are Likely to Develop Psoriatic Arthritis



- Skin disease precedes joint disease in >80% of patients
- Severity of skin disease and the severity/course of psoriatic arthritis do not correlate with each other
- 60% of patients with psoriatic arthritis progress to permanent joint destruction if left untreated

## Early Referral to a Specialist is Critical for Psoriasis Patients with Joint Symptoms and Comorbidities (e.g., CV Disease)







Early detection and appropriate treatment of psoriatic arthritis in patients with psoriasis can reduce long-term disability and minimize the need for healthcare resources

Patients with severe or complicated symptoms require care from a multidisciplinary team of providers to manage skin, joint, and cardiovascular involvement over the long term

### Summary



- Psoriasis is a common, chronic, inflammatory skin condition associated with significant morbidities
- Comorbidities must be recognized and appropriately managed
- The primary goals of treatment include clearing the skin, minimizing adverse events, addressing comorbidities, and enhancing patient quality of life
- Patient preference should be considered when selecting therapy
- Multiple treatment options are now available
- Dermatologists should screen for joint involvement in their psoriasis patients and collaborate with rheumatologists to adequately manage both skin and joint involvement over the long term



## Current Evidence-Based Recommendations for the Treatment of Psoriatic Arthritis

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Clinical Professor of Medicine David Geffen School of Medicine University of California-Los Angeles

## Learning Objective

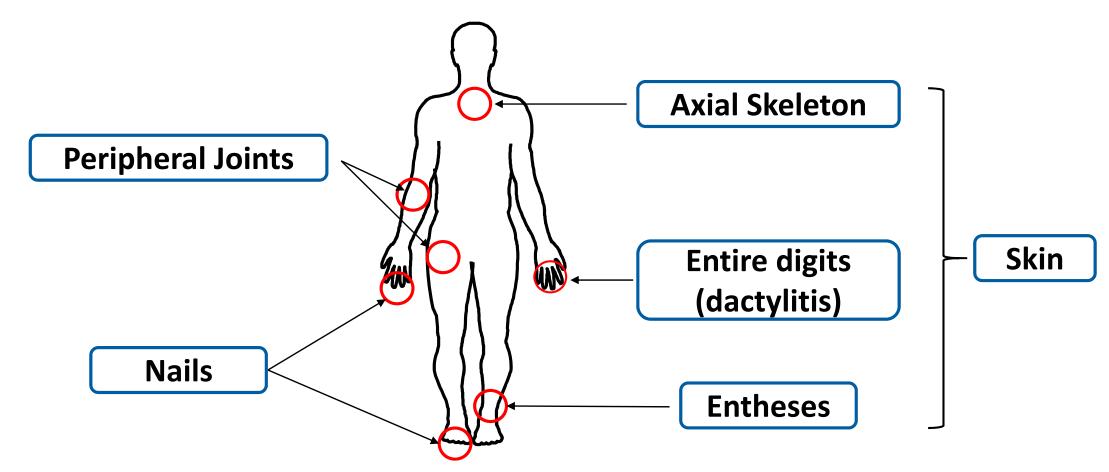


 Align psoriatic arthritis therapy with evidence-based treatment recommendations

# Psoriatic Arthritis is a Common Chronic Inflammatory Disease



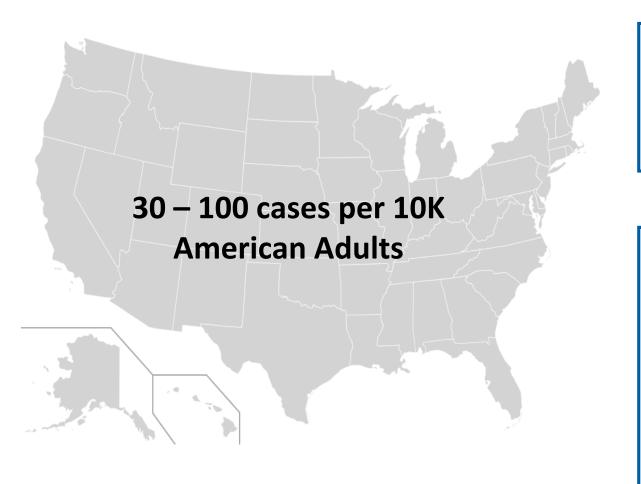
• **Psoriatic arthritis (PsA):** a progressive disorder ranging from mild synovitis to severe progressive erosive arthropathy that affects several body areas



Pipitone N, Kingsley GH, Manzo A, Scott DL, Pitzalis C. Rheumatology (Oxford). 2003;42(10):1138-48.

### Prevalence of Psoriatic Arthritis in the US

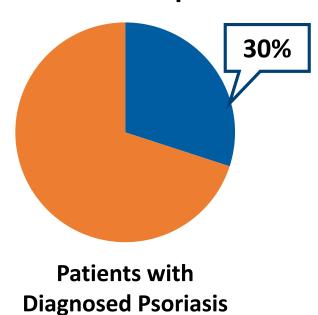




Peak incidence occurs at ages 30-55

Affects males and females equally

Occurs in up to 30% of individuals with psoriasis



Ritchlin CT, Colbert RA, Gladman DD. *N Engl J Med.* 2017;376(10):957-970.

## Psoriatic Arthritis has a Heterogeneous Clinical Presentation





**Asymmetric Oligoarthritis** 



**Dactylitis** 



Distal Interphalangeal Predominant (DIP)
Synovitis



**Enthesitis** 



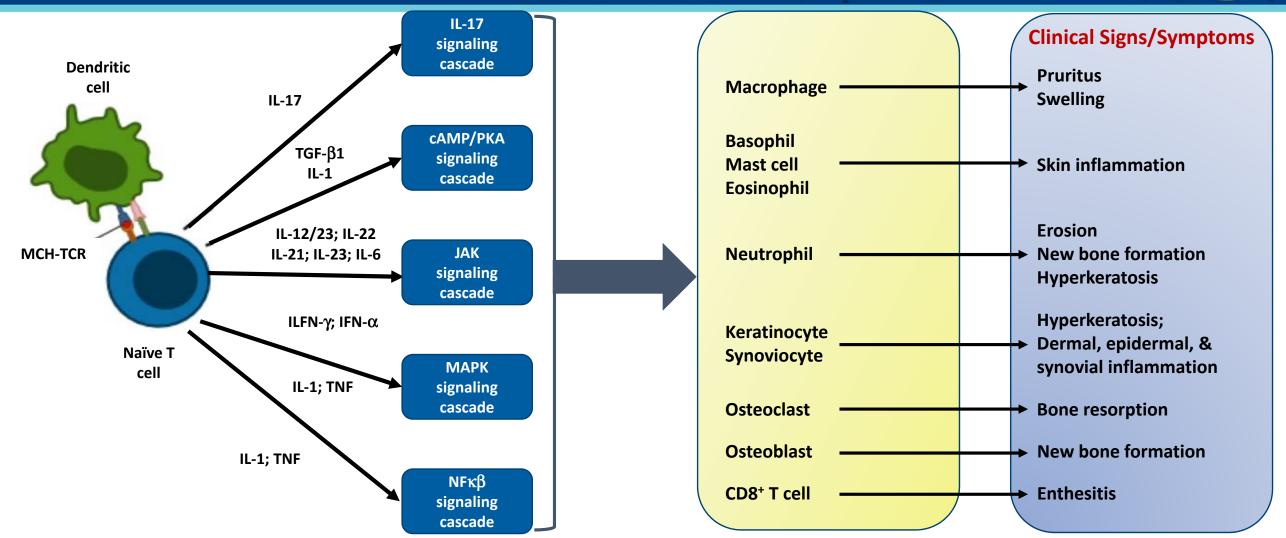
Proximal Interphalangeal Predominant (PIP)
Synovitis



**Psoriasis Plaques** 

### Pathophysiology of Psoriatic Arthritis





Coates LC, Fitzgerald O, Helliwell PS, Paul C. Semin Arthritis Rheum. 2016;46(3):291-304.; Gu C, Wu L, Li X. Cytokine. 2013;64(2):477-85.; Taskén K, Aandahl EM. Physiol Rev. 2004;84(1):137-67.; O'sullivan LA, Liongue C, Lewis RS, Stephenson SE, Ward AC. Mol Immunol. 2007;44(10):2497-506.; Mavers M, Ruderman EM, Perlman H. Curr Rheumatol Rep. 2009;11(5):378-85.; Tak PP, Firestein GS. J Clin Invest. 2001;107(1):7-11.; Mensah KA, Schwarz EM, Ritchlin CT. Curr Rheumatol Rep. 2008;10:311-

## A Diagnosis is Based on Clinical, Laboratory and Radiographic Findings



#### **Clinical**

- Psoriasis of skin and nails
- Peripheral arthritis
- Distal interphalangeal involvement
- Dactylitis
- Enthesopathy

#### **Laboratory**

- Absence of rheumatoid factor (RF) and anticitrullinated protein antibodies (ACPA)\*
- Elevated acute phase (vs. rheumatoid arthritis)

\*low levels of RF and ACPA found in 5% -16% of patients

#### Radiographic

- Erosions and resorptions
- Joint space narrowing or involvement of entheseal sites
- Bony spurs
- Spinal disease†

†sacroiliitis occurs in 40% -70% of patients

## A Delay in Diagnosis is Associated with Worse Outcomes



• Delay in diagnosis >6 months from onset of symptoms is associated with



#### **Erosive Disease**

Odds ratio: 4.6



Odds ratio: 10.6



#### **Functional Disability**

Odds ratio: 2.2



#### **Sacroiliitis**

Odds ratio: 2.3



#### **Drug-free Remission**

Odds ratio: 0.4

#### **Deformed Joints**

Odds ratio: 2.3



## Screen Patients with Suspected PsA to Minimize the Risk of Irreversible Joint Damage



#### **Symptom Recognition**

- General symptoms
  - Fatigue
  - Morning stiffness >30 min
- Joint symptoms
- Reduced range of motion
- Stiffness, pain, throbbing, swelling and tenderness in ≥1 joints
  - Swollen fingers and toes

#### **Screening Tools**

- Psoriasis Epidemiology Screening Tool (PEST)<sup>1</sup>
- Toronto Psoriasis Arthritis Screen (ToPAS)<sup>2</sup>
- Psoriatic Arthritis Screening Evaluation tool (PASE)<sup>2</sup>
- Psoriatic Arthritis Screening
   Questionnaire (PASQ)<sup>3</sup>
- Early Arthritis for Psoriatic
   Patients (EARP)<sup>4</sup>

1. Ibrahim GH, Buch MH, Lawson C, Waxman R, Helliwell PS. *Clin Exp Rheumatol.* 2009;27(3):469-74.; 2. Gladman DD, Schentag CT, Tom BD, et al. *Ann Rheum Dis.* 2009;68(4):497-501.; 3. Dominguez PL, Husni ME, Holt EW, Tyler S, Qureshi AA. *Arch Dermatol Res.* 2009;301(8):573-9.; 4. Khraishi M, Landells I, Mugford G. *Psoriasis Forum.* 2010;16:9-16; 5. Tinazzi I, Adami S, Zanolin EM, et al. Rheumatology (Oxford). 2012;51(11):2058-63..

## Measures of PsA Disease Activity



Composite Measures of Disease Activity		Comment
MDA	Minimal Disease Activity	
CPDAI	Composite Psoriatic Disease Activity Index	First composite measure of PsA disease activity
DAPSA	Disease Activity in Psoriatic Arthritis Score	
PASDAS	Psoriatic Arthritis Disease Activity Score	Reliable and holistic composite index to measure disease activity
RAPID3	Routine Assessment of Patient Index Data 3	

## Updated PsA Treatment Guidelines: Released in December 2018





Arthritis Care & Research Vol. 71, No. 1, January 2019, pp 2-29 DOI 10.1002/acr.23789 © 2018, American College of Rheumatology

#### SPECIAL ARTICLE

### 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis

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- Evidence-based pharmacologic and nonpharmacologic recommendations on the management of
  - Treatment-naive patients with active PsA
  - Patients who have active PsA despite therapy
- Focus is on optimal disease management using a treat-to-target approach
- Also includes recommendations regarding use of drugs in the presence of comorbidities (e.g., inflammatory bowel disease, diabetes, serious infection)

### Treatment Objective



### Treat-to-target strategy to optimize patient care

- Use quantitative measures (e.g., PASDAS) of disease activity to maximize achieving very low disease activity or remission
- An integrated approach to therapeutic intervention

#### Remission

 The absence of clinical and laboratory evidence of significant inflammation or minimal disease activity

PASDAS=Psoriatic Arthritis Disease Activity Score

### Treatment Algorithms and Switching



- Tailor treatment for individual patients, taking into account...
  - Disease activity and severity
  - Prognostic factors
  - Comorbidities
  - Cardio-metabolic risk factors
  - Treatment history
  - Access to therapies
  - Repeated evaluations
  - Patient preference
- Incorporate assessment and management of psychological and physical concerns of patients

Gossec L, Smolen JS, Ramiro S, et al. *Ann Rheum Dis.* 2016;75:499-510; Merola JF, Lockshin B, Mody EA. *Semin Arthritis Rheum.* 2017;47(1):29-37.; Husni ME, Merola JF, Davin S. *Semin Arthritis Rheum.* 2017;47(3):351-360.

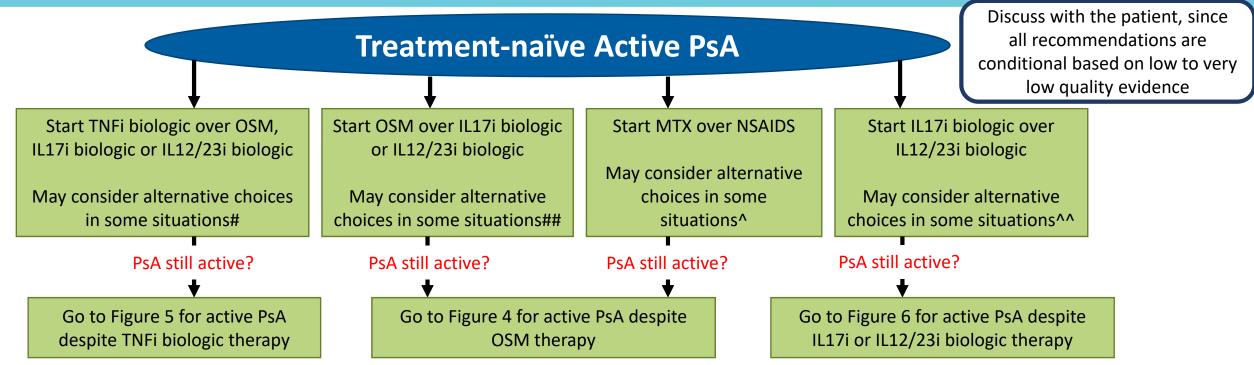
## Non-Pharmacologic, Symptomatic, and Pharmacologic Therapies for PsA



Non-pharmacologic Therapies	Physical/occupational therapy; weight loss; smoking cessation; exercise	
Symptomatic Treatments	NSAIDS, glucocorticoids	
Oral Small Molecules	Methotrexate; sulfasalazine; cyclosporine; leflunomide; apremilast	
TNF Inhibitors	Etanercept; infliximab; adalimumab; golimumab; certolizumab pegol	
IL-12/23 Inhibitors	Ustekinumab	
IL-17 Inhibitors	Secukinumab; ixekizumab	
CTLA4-Ig	• Abatacept	
JAK Inhibitors	• Tofacitinib	

## Recommendations for Treatment-Naïve Patients with Active Disease





# May consider alternatives (in parentheses) if patient has severe psoriasis (IL17i or IL12/23i); has contraindications to TNFi including recurrent infections, CHF, or demyelinating disease (OSM, IL17i, or IL12/23i); prefers oral medications (OSM) or less frequent administration (IL12/23i); has concern over starting biologic as 1st line therapy (OSM); or does not have severe psoriasis or severe PsA (OSM).

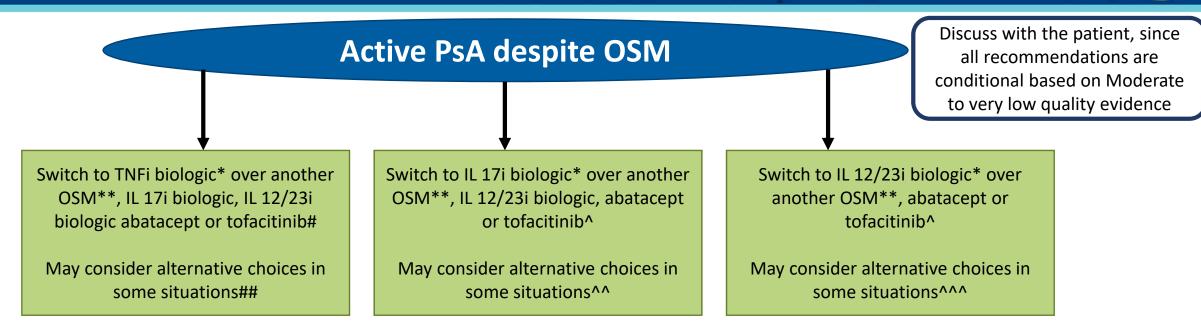
## May consider alternatives if patient has severe psoriasis or severe PsA (IL12/23i or IL17i); has concomitant active IBD (IL12/23i); or prefers less frequent administrations (Il12/23i).

- ^ May consider NSAIDs in patients with less active disease, after careful consideration of the CV and renal risks of NSAIDs.
- ^^ May consider IL12/23i if patient has concomitant IBD or desires less frequent drug administration.

The order of listing of various conditional recommendations or of different treatment choices within a conditional statement does not indicate any sequence in which treatment options would be chosen; each conditional statement stands on its own.

## Recommendations for Patients with Active Disease Despite Oral Small Molecule Therapy





- \*For each biologic, biologic monotherapy is conditionally recommended over biologic + MTX combination therapy.
- \*\* Add apremilast over switching to apremilast; switch to another OSM (except apremilast) over adding another OSM.
- # See algorithm for treatment options if patient has active PsA despite TNFi.
- ^ See algorithm for treatment options if patient has active PsA despite IL17i or IL12/23i.
- ## May consider alternatives if patient has severe psoriasis (IL17i or IL12/23i); has contraindications to TNFi including recurrent infections, CHF, or demyelinating disease (OSM, IL17i, IL12/23i, abatacept, tofacitinib); prefers oral medications (OSM, tofacitinib) or less frequent administration (IL12/23i).
- ^^ May consider alternatives if patient has concomitant active IBD (IL12/23i); absence of severe psoriasis or PsA (OSM); has recurrent serious infections (abatacept); has recurrent candida infections (tofacitinib); prefers oral medications (OSM, tofacitinib) or less frequent administrations (IL12/23i).
- ^^^ May consider alternatives if patient has absence of severe psoriasis or severe PsA (OSM); has recurrent or serious infections (abatacept); prefers oral medications (OSM, tofacitinib).

## Recommendations for Patients with Active Disease Despite Anti-TNF Therapy



Discuss with the patient, since all recommendations are conditional based **Active PsA despite TNFi biologic** on low to very low quality evidence **Despite TNFi** Despite TNFi +MTX Monotherapy Combination therapy Switch to different TNFi Switch to IL 12/23i Switch to Different Switch to IL 17i Switch to IL17i Switch to IL 12/23i biologic\* over IL 17i biologic monotherapy biologic\* aver IL 12/23i biologic monotherapy biologic\* over TNFi biologic + MTX biologic, IL 12/23i biologic, over IL17i biologic + over IL 12/23i biologic biologic, abatacept or abatacept or over TNFi biologic abatacept, tofacitinib or tofacitinib tofacitinib MTX + MTX monotherapy adding MTX May consider May consider May consider May consider May consider May consider alternative alternative choices in choices in some situations# some situations## some situations### some situations^^ some situations^^^ some situations^

## May consider alternatives if the patient has IBD (IL12/23i, tofacitinib); prefers IV dosing (abatacept); has recurrent or serious infections (abatacept); prefers oral therapy (tofacitinib); history of recurrent candida infections (tofacitinib); or prefers less frequent drug administration (IL12/23i).

### May consider alternatives if patient prefers IV dosing (abatacept); has recurrent or serious infections (abatacept); or prefers oral therapy (tofacitinib).

^^^ May consider the alternative IL12/23i+ MTX if patient has a partial response to the existing regimen or in patients with concomitant uveitis, as uveitis may respond to MTX therapy. Continuing MTX during transition to an IL12/23i was discussed as potentially beneficial to allow the new therapy time to work.

<sup>\*</sup>For each biologic, biologic monotherapy is conditionally recommended over biologic + MTX combination therapy.

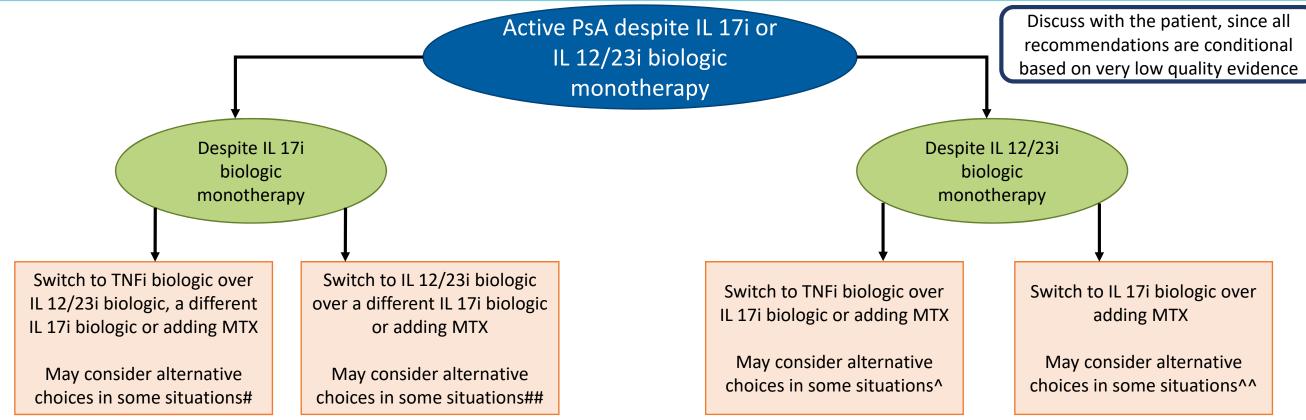
<sup>#</sup> May consider alternatives if patient has primary TNFi efficiency failure (IL17i, IL12/23i, abatacept, tofacitinib); has TNFi-associated serious adverse event (IL17i, IL12/23i, abatacept, tofacitinib); patient has demonstrated partial response to current TNFi, especially if the TNFi is a monoclonal antibody (adding MTX); prefers an oral therapy (tofacitinib); has severe psoriasis (IL17i); or prefers less frequent administration (IL12/23i).

<sup>^</sup> May consider alternative TNFi monotherapy if patient has demonstrated MTX-associated adverse events, prefers fewer medications or perceives MTX as a burden.

<sup>^^</sup> May consider alternative IL17i + MTX if patient has a partial response to the existing regimen or in patients with concomitant uveitis, as uveitis may respond to MTX therapy. Continuing MTX during transition to an IL17i was discussed as potentially beneficial to allow the new therapy time to work.

## Recommendations for Patients with Active Disease Despite IL17 or IL12/23 Monotherapy





# May consider alternatives if patient has contraindications to TNFi including recurrent infection, CHF, or demyelinating disease (switching to IL12/23i or a different IL17i or adding MTX to current regimen); if the patient had secondary efficacy failure (initial response, but lack of response/efficacy with continued use) to the current IL17i (different IL17i); severe psoriasis (different IL17i); if the patient had a partial response to the existing regimen (adding MTX to current regimen); or prefers less frequent administrations (IL12/23i).

## May consider alternatives if the patient had a secondary efficacy failure to current IL17i (different IL17i); severe psoriasis (different IL17i); or if the patient had a partial response to the

## May consider alternatives if the patient had a secondary efficacy failure to current IL17i (different IL17i); severe psoriasis (different IL17i); or if the patient had a partial response to the existing regimen (adding MTX to current regimen).

^ May consider alternatives if patient had contraindications to TNFi including recurrent infections, CHF, or demyelinating disease (switching to IK17i or adding MTX to current regimen). 
^^ May consider adding MTX in patients with only partial response to current therapy or in those who potentially have not had enough time to adequately respond.

## Biologics and Small Molecules in Late Stage Development for PsA



Agent	Therapeutic Target/Route of Administration	Status
BCD-085	<ul><li>IL-17 inhibitor</li><li>Self-injection</li></ul>	Phase 3
BMS-986165	<ul><li>TYK2 kinase inhibitor</li><li>Oral</li></ul>	Phase 3
Bimekizumab	<ul><li>IL-17A and IL-17F inhibitor</li><li>Self-injection</li></ul>	Phase 3
Brodalumab	<ul><li>IL-17 inhibitor</li><li>Self-injection</li></ul>	Phase 3
Guselkumab	<ul><li>IL-23p19 inhibitor</li><li>Self-injection</li></ul>	Phase 3
Risankizumab	<ul><li>IL-23p19 inhibitor</li><li>Self-injection</li></ul>	Phase 3
Upadacitinib	<ul><li>JAK inhibitor</li><li>Oral</li></ul>	Phase 3

Drugs in the Pipeline for Psoriasis and Psoriatic Arthritis. National Psoriasis Foundation website. https://www.psoriasis.org/drug-pipeline. Accessed March 2019.

### Summary



- Early diagnosis and treatment can stop or minimize joint damage and promote clearing of skin psoriasis
- Be aware of comorbidities and their potential impact on treatment
- Engage patients using a multi-disciplinary and collaborative approach to screening and treatment
- Apply evidence-based treat-to-target strategies to improve patient outcomes
- Educate patients on the range of available treatments and new options



# Specialty Pharmacy Management Opportunities for Psoriatic Disease

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Senior Vice President, Specialty Pharmacy

OptumRx®/BriovaRx®

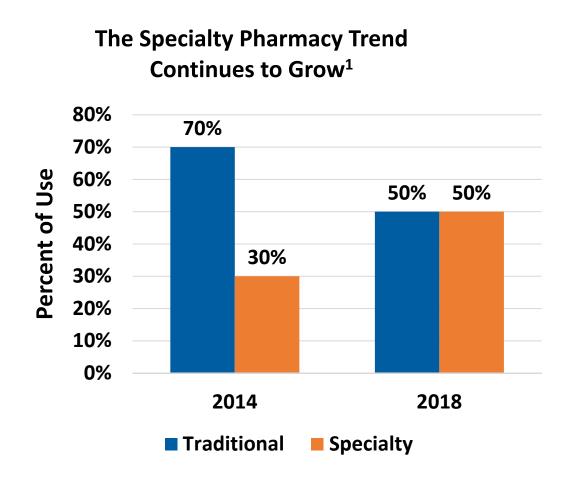
### Learning Objectives

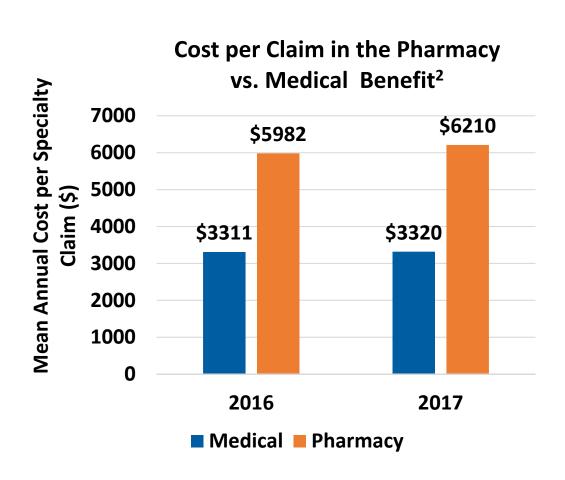


- Employ specialty pharmacy management services to improve outcomes in psoriatic disease patients
- Utilize care pathways to improve access to, and manage the cost of, psoriatic disease care

## Pharmacy Spending on Specialty Drugs Expected to Increase as Coverage Shifts From the Medical Benefit







- 1. Latest trends and best practices in pharmacy management. Express Scripts website. http://www.connerstrong.com/wp-content/uploads/2018/03/2016-Pharmacy-Cost-Trends-Presentation.pdf. Published April 12, 2016. Accessed March 2019.
- 2. Artemetrx. State of specialty spend and trend. 2017. Published September 2018.

## Benefits of Health System Specialty Pharmacy Coordinated Care



- A growing number of health systems and large hospitals report having specialty pharmacy capabilities
- Benefit of in-house specialty pharmacy services
  - Accelerate a patient's speed-to-therapy
  - Improve quality of care through integrated clinical coordination
  - Access to a patient's information via the EHR, enabling the health system specialty pharmacist to work directly with providers as an active member of the care team
  - Improved communication, therapy management and patient interventions
  - Manage adherence and financial barriers

Chambers K. The case for the health system specialty pharmacy coordinated care model. Becker's Hospital Review website. <a href="https://www.beckershospitalreview.com/pharmacy/the-case-for-the-health-system-specialty-pharmacy-coordinated-care-model.html">https://www.beckershospitalreview.com/pharmacy/the-case-for-the-health-system-specialty-pharmacy-coordinated-care-model.html</a>. Published August 22, 2018. Accessed April 2019.

## The Challenge of Managing the Cost of Psoriatic Disease Care While Improving Outcomes

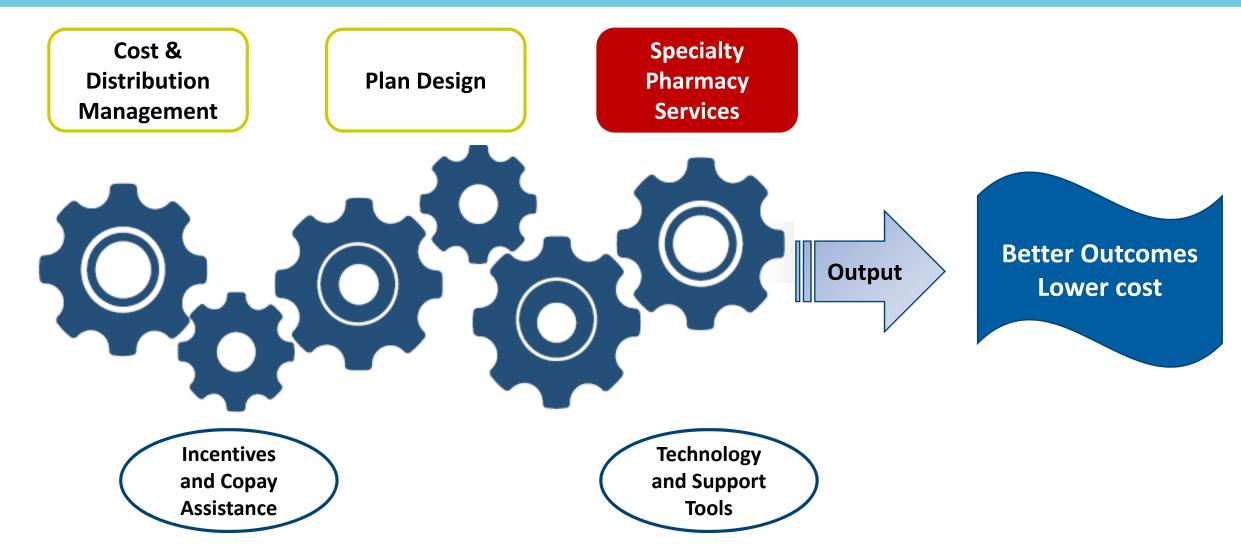


- Psoriatic disease is chronic and progressive
- It negatively impacts patient quality of life and places a significant economic burden on patients, employers, and payers
- The challenge is to identify opportunities to reduce costs while maintaining quality



## Specialty Pharmacy Services Can Contribute to Better Outcomes and Lower Costs





#### Components of Specialty Pharmacy Service



#### **Clinical Services**

- Health care provider access
- Physician consultations
- Care management

#### **Outcomes**

- Care management
- Clinical outcome measures
- Patient adherence programs
- Patient care quality measures
- REMs programs

#### **Drug Affordability**

- Insurance navigation
- Patient assistance
- Plan optimization

#### **Operational Services**

- Supply chain management
- Quality control measures
- Coordination of care

Specialty pharmacy services. Pharmaceutical Care Management Association website. https://www.pcmanet.org/pcma-cardstack/what-services-do-specialty-pharmacies-provide/. Accessed March 2019.

PBM specialty pharmacies improve patient outcomes and reduce costs. Pharmaceutical Care Management Association website. https://www.pcmanet.org/wp-content/uploads/2017/04/PBM-Specialty-Pharmacies-Improve-Patient-Outcomes-and-Reduced-Costs\_whitepaper\_final.pdf. Accessed March 2019.

## Specialty Pharmacy is an Important Contributor to Integrated Care Delivery



#### **Specialty Pharmacy Links Care Providers**

Physician

**Payer** 

**Pharma** 

#### Results

- Safety
- Adherence
- Education
- Improved outcomes

#### **Patient Data**

- Lab values
- Medical history and exam results
- Treatment history and current plan

#### **Adherence and Benefits**

- Benefit design
- Fill/refill history
- Prior authorization
- Step edits
- Copay support

#### **Safety and Outcomes**

- Safety and efficacy data
- Dosage and administration
- Storage and handling
- Cost-effectiveness data

## Specialty Pharmacy Plays a Significant Role in the Patient Journey

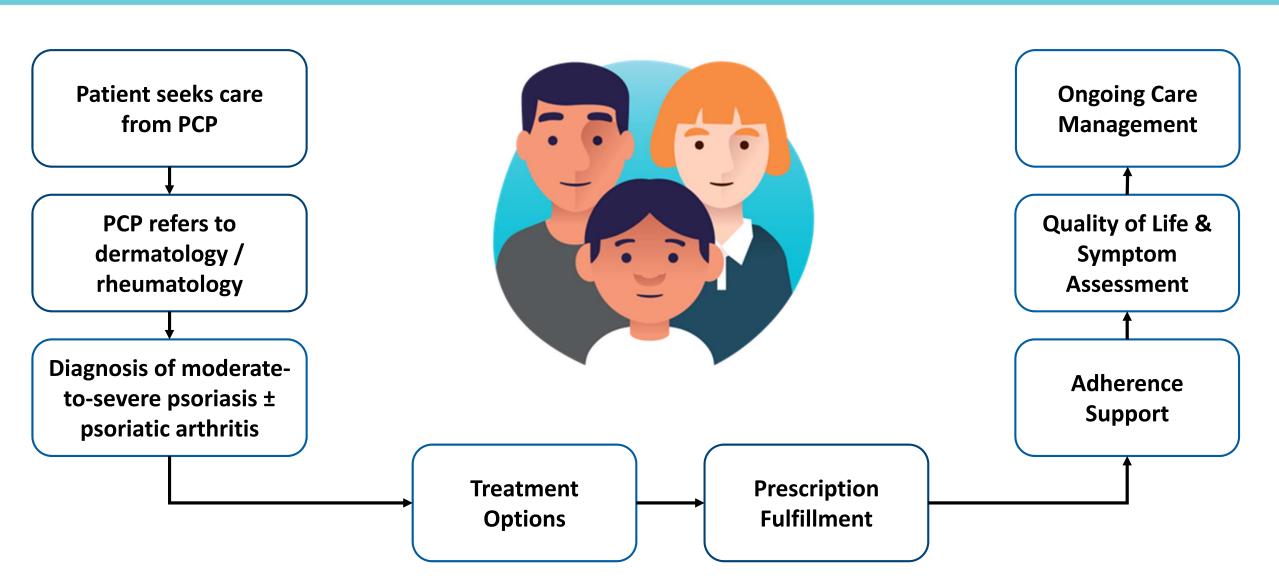


- Patients are playing a larger role in their health care requiring them to be informed about making care decisions
- Patients are now more likely to choose settings that offer them optimum care and attention
- Pharmacy is the most frequently used health benefit
  - Specialty pharmacy can significantly impact the patient journey as patients prescribed specialty drugs often face clinical and financial challenges
  - As a result, compassionate, integrated care is crucial to a favorable patient experience
- Patient access to specialty pharmacy products is an important part of the approach to fully integrated health care

Hatwig C, Zabriski S. Specialty Pharmacy Times. https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2018/november-2018/health-system-specialty-pharmacies-becoming-an-industry-cornerstone. Published November 14, 2018. Accessed March 2019.

#### The Psoriatic Disease Patient Journey





## Specialty Pharmacy Places the Focus on Individualizing Patient Care



#### **Disease and Treatment Variables**

- Disease severity
- Presence of comorbidities
- Treatment efficacy
- Treat-to-target
- Tolerability/drug interactions
- Adherence

#### **Health Care Delivery Variables**

- Patient education
- Provider-patient relationship
- Patient empowerment
- Medication therapy management
- Medication reminders
- Routine monitoring and adjustment of therapy
- Coordinated, multidisciplinary care

### Patient-Focused Specialty Pharmacy Services: *Pre-Dispense* Activities



### Benefit Investigation

- Initial claim review
- Test claim to assess eligibility (e.g., formulary, step therapy, other payer requirements)

#### **Approval**

- Statement of Medical Necessity
- Prior authorization

#### Financial Assistance

- Copay program
- Manufacturer patient assistance programs
- Alternative coverage organizations (e.g., grants, foundations)

### Patient-Focused Specialty Pharmacy Services: Post-Dispense Activities



#### Patient Education

 Educate patients (and caregivers) about the disease and their prescribed therapy

### **Adherence Monitoring**

 Ensure patients fill/refill their Rx and understand the importance of sticking with their treatment regimen

### Patient Monitoring

 Provide information and resources to address clinical, emotional, and financial barriers to treatment success

### Provider Communication

• Communicate with patients' providers regarding response and adherence to medication



### The Value of Specialty Pharmacy Services

## Impact of a Specialty Pharmacy on Adherence to Specialty Medications



#### Design

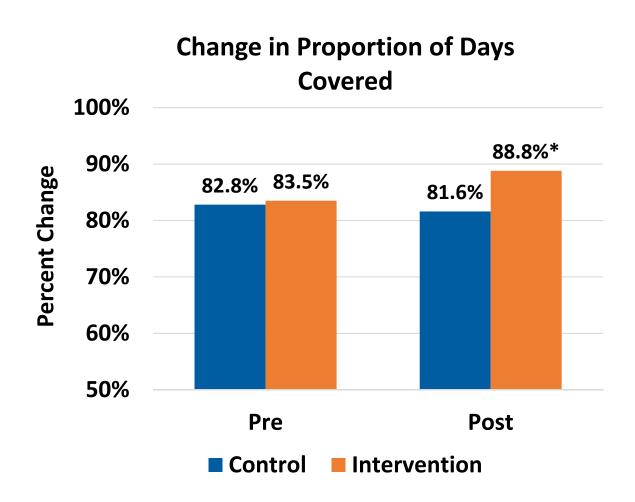
- Retrospective assessment of the impact of specialty pharmacy service model vs. usual pharmacy care on adherence to specialty medications
- Primary outcome measure tracked for 12 months before and after program implementation
  - Proportion of days covered
  - First fill persistence

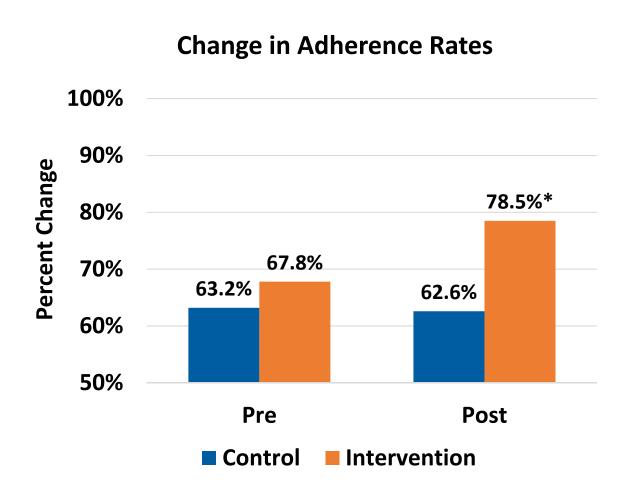
#### Intervention

- Clinical consultations specific to medication and disease state
- Additional support with cost and insurance processing
- Medication delivery options including shipping to the
  - Patient's home
  - Doctor's office
  - Convenient store location

## Use of a Specialty Pharmacy Increased Adherence to Specialty Medications



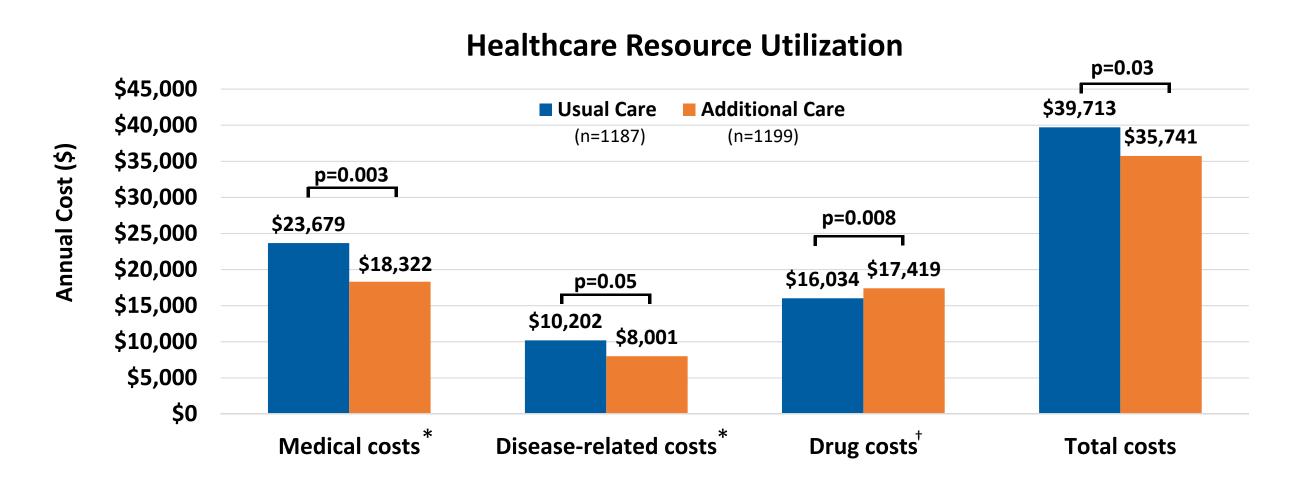




\*p<0.0001 vs. control

## Medical Costs Were Significantly Lower for Patients Who Received Additional Support





<sup>\*</sup>reduction due to reduced need for inpatient care; increase due to greater use of disease-related biologic agents.

Rubin DT, Mittal M, Davis M, Johnson S, Chao J, Skup M. J Manag Care Spec Pharm. 2017;23(8):859-867.



### Care Pathways

## Care Pathways: A Tool to Manage Patient Care and Improve Outcomes



- **Definition:** a proactive, multidisciplinary treatment plan
- Pathways provides guidance on:
  - Medical decision making
  - Psychosocial management
  - Ancillary services that go with that treatment
- **Goal:** make the treatment of complex, high-cost diseases as cost-effective as possible by improving quality, reducing variation, and increasing efficient use of healthcare
- Pathways are generally expected to reduce the overall costs of treatment
  - Many are designed to encourage efficient use of medical resources, particularly specialty drugs

#### Why Use Care Pathways?

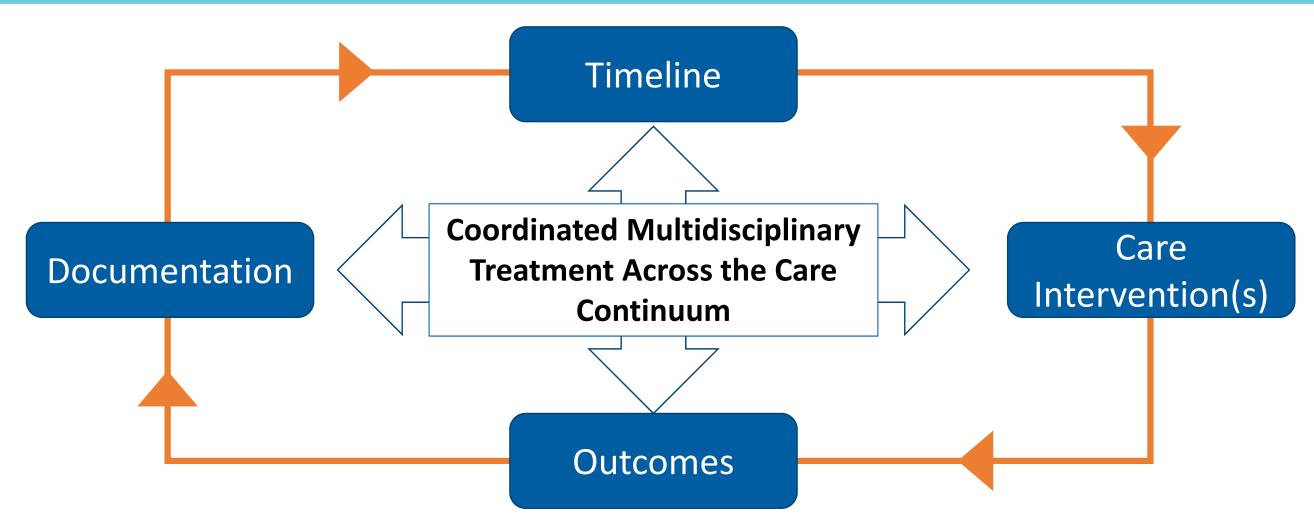


- Reinforce patient-centered care
- Enhance interdisciplinary collaboration
- Reduce unnecessary variation in patient care
- Incorporate local and national guidelines into routine clinical practice
- Support alignment with evidence-based standards of care
- Optimize management of health care resources



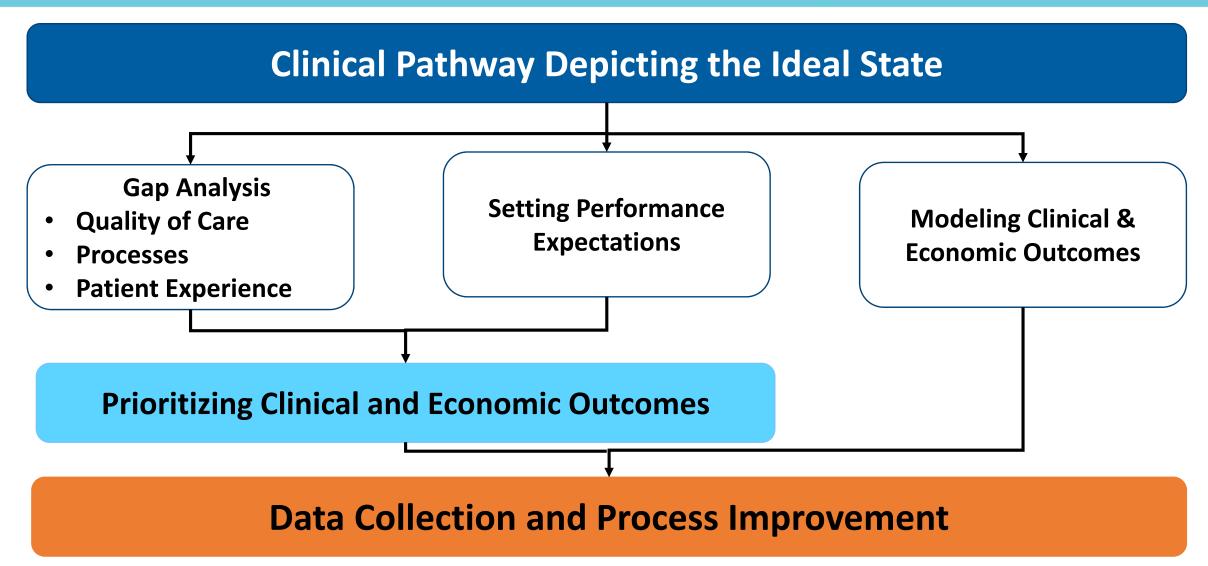
### Primary Components of a Care Pathway





## Clinical Pathways Serve as an Analytical Framework for Quality Improvement





## Care Pathways Can Be Used to Enhance Psoriatic Disease Management



 Increase awareness of psoriatic arthritis among patients, primary care providers and dermatologists

- Promote the use of screening tools to identify early symptoms and ensure timely referral
- Develop referral pathways

- Perform regular monitoring of patient progress
- Manage comorbidities
- Document outcome



**Pre-Diagnosis** 

**Referral & Diagnosis** 

Treatment Initiation & Management

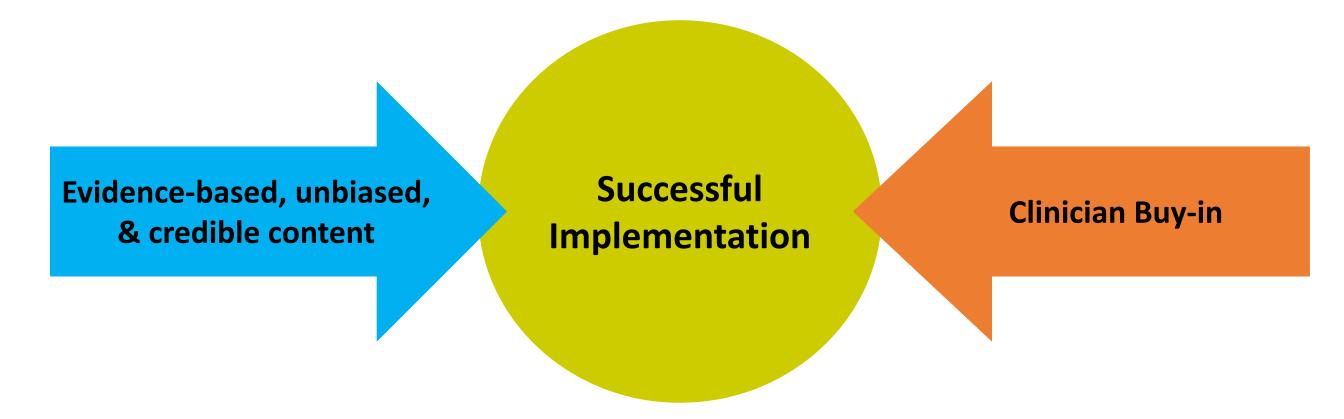
**Follow Up** 

- Promote collaborative care between dermatologists and rheumatologists
- Employ a multidisciplinary care team to provide comprehensive care

- Provide evidence-based care
- "Treat-to-target"; optimize treatment based on response to therapy
- Engage patients in their care

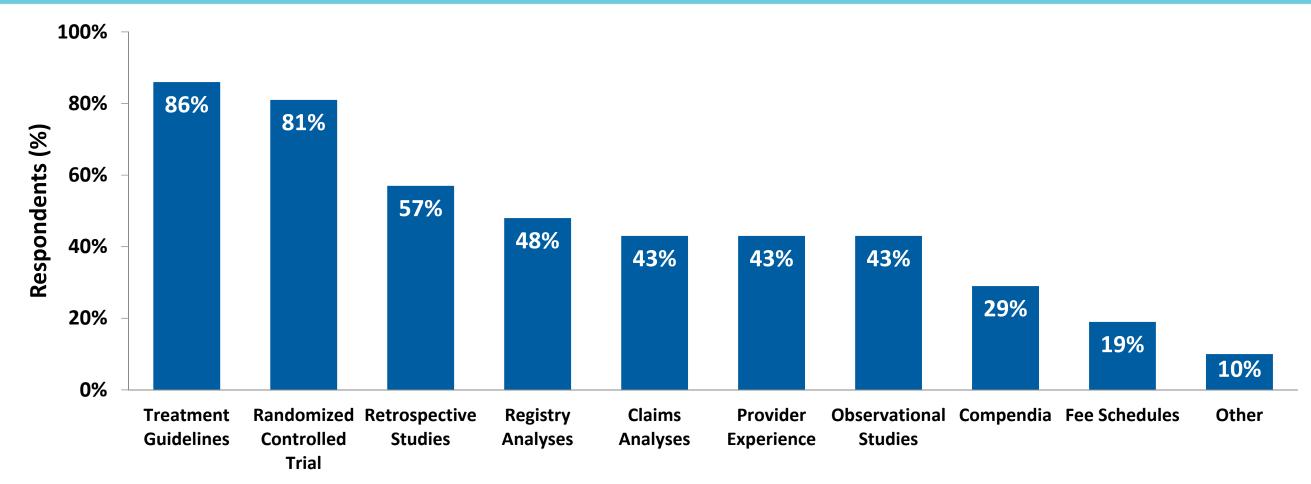
## Critical Components Necessary for Successful Pathway Implementation





### Data Sources for Pathway Development





N=26 respondents to an on-line survey: medical directors (n=8); pharmacy directors (n=2); physicians (n=9); pathway vendors (n=7). Medical and pharmacy directors represented managed care organizations, integrated delivery systems, and pharmacy benefit managers that covered a total of approximately 60 million lives.

Chawla A, Westrich K, Matter S, Kaltenboeck A, Dubois R. Am J Manag Care. 2016;22(1):53-62.

### Criteria for High-Quality Clinical Care Pathways



- Developed by clinical experts
- Up-to-date, evidence-based and clinically sound
- Transparent
- Patient-focused
- Comprehensive
- Supports clear and achievable outcomes

- Seamlessly integrated with information technology and decision supports tools
- Allows for efficient and effective communication and adjudication
- Efficient reporting of metrics
- Outcomes-driven results
- Promotes continuous quality improvement

### Pharmacy Role in Clinical Pathways



Role	Activities
Medication therapy management	Medication selection; review of high-risk medications
Medication assistance	Identify need; assist in obtaining medication during transitions of care
Patient and family educator	Educate family and patient on medication changes, side effects, expected outcomes
Medical staff educator	Educate staff on medication place in therapy, duplications, optimal timing, drug interactions; assist in creation of educational materials
Revise and establish policies and protocols	Review current policies in place and recommend amendment based upon changes in evidence-based medicine or to reflect clinical pathway management
Research and evaluate outcomes	Complete medication use evaluations; create reports and present to leadership

#### Barriers to Pathways Expansion



- Lack of transparency in pathway development, modification, and maintenance
- Lack of patient perspective in the development process
- Interference of the pathway in the patient-provider treatment decision making process
- Lack of interoperability and integration between the pathway IT infrastructure and the patient electronic medical record
- Lack of accountability for the quality, effectiveness, and transparency of pathways

### Summary



- Psoriatic disease is a chronic and progressive condition that places a significant economic burden on patients, employers, and payers
- The challenge is to identify opportunities to reduce costs while maintaining quality of care
- Specialty pharmacy services and care pathways may be useful strategies to ensure patients have access to and receive high-quality, evidence-based, cost-effective treatment, and multidisciplinary care