Psoriasis and Psoriatic Arthritis

Developed by:
Mike Crowe, PharmD, MBA, CSP, FMPA
Jonathan Clark, PharmD

Presented by:
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Speaker Disclosure

Michael Crowe has nothing to disclose.
Learning Objectives

At the completion of this presentation, audience members should be able to:

- Discuss the incidence and patient demographics of psoriasis and psoriatic arthritis.
- Describe the signs, symptoms, diagnosis and screening for psoriasis and psoriatic arthritis.
- Outline psoriasis and psoriatic arthritis treatment guidelines.
- Describe the appropriate pharmacologic management of psoriasis and psoriatic arthritis.

Psoriasis

Disease Overview and Presentation
Epidemiology

- Affects approximately 7.4 million people in the United States\(^1\)
  - Initial onset usually between ages 15 – 35 years
  - Higher incidence in Caucasians
- Detrimental effects include:\(^2\)
  - High degree of morbidity
  - Reduced levels of employment and income
  - Reduced quality of life
  - High costs for long-term therapy

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Pathophysiology

- Plaques
  - Hyperproliferation of keratinocytes
    - Average turnover rate of 311 hours shortened to 36 hours\(^1\)
  - Abnormal skin cell differentiation
    - Potential for scaling and silvery-white patches
  - Increased inflammatory cells
  - Vascular changes
- Potential joint involvement (psoriatic arthritis)

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Pathophysiology

AMPs = antimicrobial peptides; CCL = chemokine (C-C motif) ligand; CKCL = chemokine (C-X-C motif) ligand; IFN = interferon; IL = interleukin; Th1 = T helper type 1; Th17 = T helper type 17; TNF = tumor necrosis factor

Causes

- Exact etiology unknown
- Predisposing factors
  - Genetics\(^1\)
    - Family history increases risk
  - Environmental factors\(^2,3\)
    - Stress
    - Infections
    - Social characteristics
      - Alcohol use, smoking, obesity
    - Cold, dry weather and lack of sunlight

Exacerbating Agents

<table>
<thead>
<tr>
<th>Most Common</th>
<th>Associated</th>
<th>Less Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimalarials (e.g., hydroxychloroquine)</td>
<td>Angiotensin-converting enzyme inhibitors</td>
<td>Amiodarone</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>Antibiotics (e.g., tetracyclines)</td>
<td>Cimetidine</td>
</tr>
<tr>
<td>Lithium</td>
<td>Benzodiazepines</td>
<td>Clonidine</td>
</tr>
<tr>
<td></td>
<td>Interferons</td>
<td>Digoxin</td>
</tr>
<tr>
<td></td>
<td>Nonsteroidal anti-inflammatory drugs</td>
<td>Fluoxetine</td>
</tr>
<tr>
<td></td>
<td>Terbinafine</td>
<td>Gemfibrozil</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Imiquimod</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quinidine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tumor necrosis factor alpha inhibitors</td>
</tr>
</tbody>
</table>


Types of Psoriasis

• Plaque psoriasis
  – Affects 85 – 90% of patients
  – Thick, erythematous, sharply marginated lesions
    • Silvery-white scales often involved
    • Symmetrical and stable
  – Common sites: scalp, trunk, buttocks, and limbs
  – May experience pain, fever, chills, and/or pruritus

Types of Psoriasis

- **Guttate psoriasis**
  - Affects up to 10% of patients¹
  - Tends to occur in individuals younger than 30 years²
  - May be associated with streptococcal infections
  - Presentation includes several red droplike lesions on the trunk and limbs²

- **Inverse psoriasis**
  - Usually occurs with other forms of psoriasis
  - Highly erythematous lesions in intertriginous areas (e.g., axilla, genitals, between buttocks, submammary region)
  - Minimal scaling due to moist locations


Types of Psoriasis

- **Erythrodermic psoriasis**
  - Affects approximately 3% of patients
  - Generally occurs in those with unstable plaque psoriasis
  - Most severe type with large amounts of skin shedding
  - Can lead to itching, pain, infection, pneumonia, hypothermia, and congestive heart failure¹²

- **Pustular psoriasis**
  - Usually appears as white blisters and may be severe
  - Symptoms include malaise, fever, diarrhea, and lab value abnormalities
  - Typically occurs on a cyclical basis and affects the palms of the hands and soles of the feet³
  - May be triggered by local irritants, pregnancy, medications, infections, and systemic glucocorticoid withdrawal⁴

Comorbidities

- Patients with psoriasis are at increased risk of developing metabolic syndrome and cardiovascular disease
- Patients with psoriasis have a higher incidence of other autoimmune diseases (e.g., multiple sclerosis, Crohn’s disease) and skin cancer
- Potential for physical and mental disabilities
  – Dermatology Life Quality Index (DLQI)

Presentation

- Inflammatory arthropathy associated with psoriasis, joint pain, stiffness, and inflammation\(^1,2\)
  - Enthesitis and dactylitis
- Up to 42% of patients with psoriasis may develop psoriatic arthritis
  - Nail involvement may place patients at higher risk for joint involvement\(^3\)


Psoriatic Arthritis vs. Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Psoriatic Arthritis</th>
<th>Rheumatoid Arthritis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psoriasis</td>
<td>Yes</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Peripheral disease</td>
<td>Asymmetric</td>
<td>Symmetric</td>
</tr>
<tr>
<td>Stiffness</td>
<td>In the morning and/or with immobility</td>
<td>In the morning and/or with immobility</td>
</tr>
<tr>
<td>Female to male ratio</td>
<td>1:1</td>
<td>3:1</td>
</tr>
<tr>
<td>Enthesitis</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>High titer rheumatoid factor (RF)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Human leukocyte antigen (HLA) association</td>
<td>CW6, B27</td>
<td>DR4</td>
</tr>
<tr>
<td>Nail lesions</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Subcutaneous nodules</td>
<td>Less common</td>
<td>More common</td>
</tr>
<tr>
<td>Ocular involvement</td>
<td>Less common</td>
<td>More common</td>
</tr>
</tbody>
</table>

Onset

- Psoriatic symptoms tend to precede arthritis symptoms in 60 – 80% of cases\(^1\)
  - Usually within 10 years
- Psoriatic arthritis is underdiagnosed
  - Estimated that one-third of patients with psoriasis are undiagnosed\(^2\)
- Diagnosis is often delayed


Classification

- Classification Criteria for Psoriatic Arthritis (CASPAR)
  - Established inflammatory articular disease and at least 3 points from the following features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current psoriasis</td>
<td>2</td>
</tr>
<tr>
<td>History of psoriasis without current symptoms</td>
<td>1</td>
</tr>
<tr>
<td>Family history of psoriasis without current symptoms</td>
<td>1</td>
</tr>
<tr>
<td>History or current symptoms of dactylitis</td>
<td>1</td>
</tr>
<tr>
<td>Juxta-articular new-bone formation</td>
<td>1</td>
</tr>
<tr>
<td>Negative test result for rheumatoid factor</td>
<td>1</td>
</tr>
<tr>
<td>Nail dystrophy</td>
<td>1</td>
</tr>
</tbody>
</table>

Psoriasis and Psoriatic Arthritis

Treatment and the Pharmacist’s Role

Treatment Considerations

• Treatment regimens may change over time
• Primary goal: skin normalization
• Other goals:
  – Itch relief
  – Reduction of flares
  – Managing adverse effects
  – Improving quality of life
• The first step after diagnosis is determining the severity of the disease
Disease Severity

American Academy of Dermatology (AAD) definitions:

• Mild psoriasis
  – Less than 5% body surface area (BSA) affected

• Moderate psoriasis
  – Greater than or equal to 5%, but less than 10% BSA affected

• Severe psoriasis
  – Greater than or equal to 10% BSA affected


Rule of Nines

Disease Severity Evaluation Tools

• Psoriasis Area and Severity Index (PASI)
  – Commonly used in clinical trials
  – Score ranges from no disease (0) to maximal disease (72)
  – 75% improvement in the PASI score (PASI 75) frequently required of biologic agents prior to FDA approval

• Physician’s Global Assessment (PGA)
  – Focus on overall psoriasis severity
  – 7-point scale ranging from clear skin (0) to severe disease (6)

• Subjective measures used in clinical practice


Psoriasis Treatment Options

Treatment Guidelines

American Academy of Dermatology Decision Tree for the Treatment of Psoriasis and Psoriatic Arthritis

- Anti-TNF = tumor necrosis factor inhibitor; MTX = methotrexate; PsA = psoriatic arthritis.
- *Patients not physically limited by PsA should not automatically begin therapy with an anti-TNF agent.
- †Patients with limited disease that does not improve should not automatically begin systemic therapy because the risk of systemic therapy may outweigh the risks of the disease.


Nonpharmacologic Therapy

- Support groups and counseling
- Hygienic practices
  - Avoid harsh soaps and detergents
  - Use fragrance-free soaps
  - Use lukewarm water when showering or bathing
- Phototherapy with ultraviolet (UV) light
  - Antiproliferative and anti-inflammatory effects
  - Usually reserved for patients with less than 10% BSA involvement or pregnant women
  - Avoid in patients with a history of skin cancer
Nonpharmacologic Therapy

• Photochemotherapy (PUVA)
  – Psoralens (e.g., methoxsalen) administered topically or orally before exposure to UVA light
  – Contraindicated in pregnancy¹

• Emollients
  – Prevent evaporation from deep layers of the skin
  – Should be applied topically 1 to 3 times a day²

Pharmacologic Treatments

Topical therapy

- **Mild to Moderate Psoriasis**
  - Monotherapy

- **Severe Psoriasis**
  - Combination therapy

- Patient preference and adherence is key
- Fingertip unit (FTU) useful for application¹

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Pharmacologic Treatments

## Topical Therapies

**Calcineurin inhibitors**
- **Corticosteroids**
- **Keratolytics**
- **Retinoids**
- **Vitamin D analogs**
- **Coal tar**
- **Anthralin**

### Pharmacologic Treatments

#### Traditional systemic therapies

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication(s)</th>
<th>Typical Dose</th>
<th>Adverse Effects</th>
<th>Counseling Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acitretin (Soriatane®)</td>
<td>Severe plaque psoriasis</td>
<td>25 – 50 mg/day (lower doses may be used)</td>
<td>Hypervitaminosis A, hyperlipidemia, hepatotoxicity, gastrointestinal (GI) intolerance</td>
<td>Take with a meal, do not consume alcohol, do not donate blood</td>
</tr>
<tr>
<td>Cyclosporine (Neoral®)</td>
<td>Severe, recalcitrant plaque psoriasis</td>
<td>2.5 – 4 mg/kg/day in 2 divided doses (dose may be reduced)</td>
<td>Hypertension, elevated lipids, GI intolerance, headache, gingival hyperplasia, hair growth</td>
<td>Long-term therapy not recommended due to risk of malignancy, no live vaccinations</td>
</tr>
<tr>
<td>Methotrexate (TrexallTM)</td>
<td>Severe, recalcitrant, disabling psoriasis</td>
<td>7.5 – 25 mg once weekly; increase by 2.5 mg every 2 – 4 weeks until response (do not exceed 30 mg/week)</td>
<td>Myelosuppression, hepatotoxicity, nausea, vomiting, stomatitis, malaise, headaches, pulmonary toxicity</td>
<td>Avoid use in breastfeeding women and within 3 months of pregnancy for both men and women</td>
</tr>
</tbody>
</table>

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## Pharmacologic Treatments

### Traditional systemic therapies

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<tr>
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<th>Counseling Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leflunomide (Arava®)</strong></td>
<td>Not FDA-approved for PsO or PsA; limited data in PsA</td>
<td>Loading dose 100 mg/day for 3 days; maintenance dose up to 20 mg/day</td>
<td>Myelosuppression, hepatotoxicity, nausea, vomiting, stomatitis, malaise, headaches, pulmonary toxicity</td>
<td>Avoid use in pregnancy and nursing</td>
</tr>
<tr>
<td><strong>Sulfasalazine (Azulfidine®)</strong></td>
<td>Not FDA-approved for PsO or PsA</td>
<td>500 mg twice daily; may increase up to 3 – 4 g/day as tolerated</td>
<td>Headache, GI intolerance, anorexia, allergic reaction</td>
<td>Breastfed newborns have risk of kernicterus</td>
</tr>
<tr>
<td><strong>Tacrolimus (Prograf®)</strong></td>
<td>Not FDA-approved for PsO or PsA</td>
<td>0.05 – 0.15 mg/kg/day; appropriate duration of treatment is unknown</td>
<td>Nephrotoxicity, hypertension, elevated lipids, GI intolerance, headache, gingival hyperplasia, hair loss</td>
<td>Avoid use while breastfeeding</td>
</tr>
</tbody>
</table>

GI = gastrointestinal; PsA = psoriatic arthritis; PsO = psoriasis

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## Pharmacologic Treatments

- **Biologic therapies**
  - Generally reserved for moderate to severe psoriasis when other therapies are inadequate or contraindicated¹
  - Usually monotherapy, unless used in combination with traditional systemic therapy for psoriatic arthritis

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Biologic Therapies

- Safety considerations
  - Contraindicated in patients with active, serious infections
  - Screen for tuberculosis and hepatitis
  - Practice good hygiene
  - Increased risk of infections
    - May discontinue biologic use during infection treatment
  - Vaccinations should be up-to-date
    - Avoid live vaccinations while on biologic therapy
Biologic Therapies

• Counseling
  – Injection site and infusion reactions
    • Patients may experience pain, irritation, or rash
    • Rotate injection sites and allow the product to warm to room temperature prior to administration
  – Ensure full dose is administered before withdrawal of an injection device and dispose appropriately
  – Do not rub the injection site
  – Response to therapy may take up to 12 weeks, depending on the product

Biologic Therapies

• Tumor necrosis factor (TNF)
  – Proposed to stimulate synthesis of several inflammatory cytokines
  – Patients with psoriasis have elevated TNF levels
    • Degree of elevation corresponds with the PASI score

Biologic Therapies

- **TNF inhibitors**
  - Adalimumab (Humira®), certolizumab pegol (Cimzia®), etanercept (Enbrel®), golimumab (Simponi®), and infliximab (Remicade®)
  - **Warnings and Precautions**
    - Hepatitis B
    - Moderate to severe heart failure
    - Multiple sclerosis
    - Tuberculosis
  - Potential for decreased efficacy over time

Biologic Therapies

- **Ustekinumab (Stelara®)**\(^1\)
  - IL-12 and IL-23 inhibitor
  - Most common adverse effects are infection, fatigue, and headache

- **Secukinumab (Cosentyx®)**\(^2\)
  - IL-17A inhibitor
  - Most common adverse effects are nasopharyngitis, headache, upper respiratory tract infection, and diarrhea

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Biologic Therapies

• Ixekizumab (Taltz®)¹
  – IL-17A inhibitor
  – Most common adverse effects are injection site reactions, upper respiratory tract infections, nausea, and tinea infections

• Brodalumab (Siliq*)²
  – IL-17A inhibitor
  – Most common adverse effects are arthralgia, nasopharyngitis, upper respiratory tract infection, and headache
  – Black box warning and REMS program for suicidal ideation and behavior


Targeted Oral Therapies

• Apremilast (Otezla®)
  – cAMP specific phosphodiesterase-4 (PDE4) inhibitor
  – Most common adverse effects are diarrhea, nausea, headache, and upper respiratory tract infection¹
  – Dose titrated over 5 days to avoid gastrointestinal intolerance; adjust dose for renal impairment
  – Increased risk of depression and weight loss
  – Avoid strong CYP450 inducers (e.g., rifampin)
  – Pregnancy category C; avoid nursing

### Biologic and Targeted Oral Therapies

<table>
<thead>
<tr>
<th>Agent</th>
<th>Target</th>
<th>Indications*</th>
<th>Route and Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (Humira®)</td>
<td>TNF</td>
<td>PsO, PsA</td>
<td>• Subcutaneous injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsO: 80 mg initially, then 40 mg every other week</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>starting one week later</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsA: 40 mg every other week</td>
</tr>
<tr>
<td>Apremilast (Otezla®)</td>
<td>PDE4</td>
<td>PsO, PsA</td>
<td>• Oral tablet</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 30 mg twice daily after completion of 5-day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>titration dosing:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Day 1: 10 mg in AM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Day 2: 10 mg in AM, 10 mg in PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Day 3: 10 mg in AM, 20 mg in PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Day 4: 20 mg in AM, 20 mg in PM</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Day 5: 20 mg in AM, 30 mg in PM</td>
</tr>
<tr>
<td>Brodalumab (Siliq®)</td>
<td>IL-17A</td>
<td>Refractory PsO</td>
<td>• Subcutaneous injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 210 mg at Weeks 0, 1, and 2 followed by 210 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>every 2 weeks</td>
</tr>
<tr>
<td>Certolizumab pegol</td>
<td>TNF</td>
<td>PsA</td>
<td>• Subcutaneous injection</td>
</tr>
<tr>
<td>(Cimzia®)</td>
<td></td>
<td></td>
<td>• 400 mg initially and at Week 2 and 4, followed by</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 mg every other week; for maintenance dosing,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>400 mg every 4 weeks can be considered</td>
</tr>
<tr>
<td>Etanercept (Enbrel®)</td>
<td>TNF</td>
<td>PsO, PsA</td>
<td>• Subcutaneous injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsO: 50 mg twice weekly for 3 months, followed by</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>50 mg once weekly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsA: 50 mg once weekly with or without methotrexate</td>
</tr>
</tbody>
</table>

AM = morning; PM = evening; PDE4 = phosphodiesterase 4; PsA = psoriatic arthritis; PsO = plaque psoriasis; TNF = tumor necrosis factor. *Only FDA-approved indications for PsO and PsA are presented in this table.


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### Biologic and Targeted Oral Therapies

<table>
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<tr>
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<td></td>
<td></td>
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<td></td>
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<td></td>
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<td>• Subcutaneous injection</td>
</tr>
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<td></td>
<td></td>
<td>• PsO: 50 mg twice weekly for 3 months, followed by</td>
</tr>
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<td></td>
<td></td>
<td></td>
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<tr>
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</table>

IL-17A = interleukin-17A; PsA = psoriatic arthritis; PsO = plaque psoriasis; TNF = tumor necrosis factor.

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</tr>
</thead>
</table>
| Golimumab (Simponi®)   | TNF    | PsA          | • Subcutaneous injection  
                         |        |              | • 50 mg once a month                                   |
| Infliximab (Remicade®) | TNF    | PsO, PsA     | • Intravenous infusion  
                         |        |              | • 5 mg/kg at Weeks 0, 2, and 6, then every 8 weeks   |
| Ixekizumab (Taltz®)    | IL-17A | PsO          | • Subcutaneous injection  
                         |        |              | • 160 mg at Week 0, followed by 80 mg at Weeks 2,  
                         |        |              | 4, 6, 8, 10, and 12, then 80 mg every 4 weeks       |

IL-17A = interleukin-17A; PsA = psoriatic arthritis; PsO = plaque psoriasis; TNF = tumor necrosis factor.

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<th>Route and Dosing</th>
</tr>
</thead>
</table>
| Secukinumab (Cosentyx®)| IL-17A | PsO, PsA     | • Subcutaneous injection  
                         |        |              | • PsO: Recommended dosage is 300 mg at Weeks 0, 1, 2, 3,  
                         |        |              | and 4 followed by 300 mg every 4 weeks; for some patients, a dose of 150 mg may be acceptable  
                         |        |              | • PsA: For patients with coexistent moderate to severe PsO, use the dosage and administration for PsO; for others, administer with or without a loading dosage. Recommended dosage:  
                         |        |              | • With a loading dosage: 150 mg at Weeks 0, 1, 2, 3, and 4, then every 4 weeks thereafter  
                         |        |              | • Without a loading dosage: 150 mg every 4 weeks  
                         |        |              | • If a patient continues to have active psoriatic arthritis, consider a dosage to 300 mg per dose

IL-17A = interleukin-17A; PsA = psoriatic arthritis; PsO = plaque psoriasis.

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</tr>
</thead>
<tbody>
<tr>
<td>Ustekinumab (Stelara®)</td>
<td>IL-12/23</td>
<td>PsO, PsA</td>
<td>• Subcutaneous injection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsO: For patients weighing ≤100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. Use 90 mg per dose for patients greater than 100 kg.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• PsA: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. Use 90 mg per dose for patients with coexistent moderate to severe PsO weighing &gt;100 kg.</td>
</tr>
</tbody>
</table>

IL-17A = interleukin-17A; PsA = psoriatic arthritis; PsO = plaque psoriasis.

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## Treatment Selection

### Mild psoriasis
- First line: topical therapies, phototherapy
- Second line: short term use of systemic therapies

### Moderate or severe psoriasis
- First line: systemic agents, phototherapy, photochemotherapy, biologics

### Psoriasis with physically-limiting psoriatic arthritis
- First line: anti-TNF agent +/- methotrexate

Treatment Selection

• Caveats in AAD recommendations for moderate to severe psoriasis
  – Golimumab not recommended for patients without psoriatic arthritis
  – Ustekinumab is second line for adult patients with psoriatic arthritis, in combination with methotrexate
  – The latest AAD treatment guidelines were published before approval of apremilast, certolizumab pegol, ixekizumab, secukinumab, and brodalumab for psoriatic conditions

Pharmacist’s Role

• Ensure optimal drug therapy selection
• Educate patients on:
  – Potential adverse effects and mitigation strategies
  – Proper dosing and administration
  – Potential drug interactions
  – Efficacy expectations
  – Adherence
  – Contraindications
  – Appropriate vaccinations
Conclusion

• Pharmacists are in a favorable position to educate patients and increase their probability of success with therapy for psoriasis and psoriatic arthritis
• Pharmacist support can influence adherence, efficacy, adverse effect management, and overall health outcomes

Thank you!