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<td>ACR</td>
<td>American College of Rheumatology</td>
</tr>
<tr>
<td>ANA</td>
<td>Antinuclear antibodies</td>
</tr>
<tr>
<td>AS</td>
<td>Ankylosing spondylitis</td>
</tr>
<tr>
<td>boDMARD</td>
<td>Biologic originator disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>bo/bs DMARD</td>
<td>Biologic originator/biosimilar disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>BSA</td>
<td>Body Surface Assessment</td>
</tr>
<tr>
<td>bsDMARD</td>
<td>Biosimilar disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>CASPAR</td>
<td>CLASsification criteria for Psoriatic ARthritis</td>
</tr>
<tr>
<td>CBC</td>
<td>Complete blood count</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CHF</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>CMP</td>
<td>Comprehensive metabolic panel</td>
</tr>
<tr>
<td>CRP</td>
<td>C-reactive protein</td>
</tr>
<tr>
<td>csDMARD</td>
<td>Conventional synthetic disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>CV</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>DIP</td>
<td>Distal interphalangeal</td>
</tr>
<tr>
<td>DMARD</td>
<td>Disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>DMPA</td>
<td>Depot medroxyprogesterone acetate</td>
</tr>
<tr>
<td>ESR</td>
<td>Erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>EULAR</td>
<td>European League Against Rheumatism</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GI</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>GRAPPA</td>
<td>Group for Research and Assessment of Psoriasis and Psoriatic Arthritis</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C virus</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>HLA-B27</td>
<td>Human leukocyte antigen-B27</td>
</tr>
<tr>
<td>HPV</td>
<td>Human papilloma virus</td>
</tr>
<tr>
<td>IBD</td>
<td>Inflammatory bowel disease</td>
</tr>
<tr>
<td>IBP</td>
<td>Inflammatory back pain</td>
</tr>
<tr>
<td>IL-12/23i</td>
<td>Interleukin-12/23 inhibitor</td>
</tr>
<tr>
<td>IL-17i</td>
<td>Interleukin-17 inhibitor</td>
</tr>
<tr>
<td>IUD</td>
<td>Intrauterine devices</td>
</tr>
<tr>
<td>IVF</td>
<td>In vitro fertilization</td>
</tr>
<tr>
<td>JAKi</td>
<td>Janus Kinase inhibitor</td>
</tr>
<tr>
<td>LFT</td>
<td>Liver function test</td>
</tr>
<tr>
<td>MDA</td>
<td>Minimal disease activity</td>
</tr>
<tr>
<td>MDG</td>
<td>Physician Global Assessment</td>
</tr>
<tr>
<td>MDHAQ</td>
<td>Multidimensional Health Assessment Questionnaire</td>
</tr>
<tr>
<td>MMR</td>
<td>Mumps, measles and rubella (vaccine)</td>
</tr>
<tr>
<td>MTX</td>
<td>Methotrexate</td>
</tr>
<tr>
<td>MTXPG</td>
<td>Methotrexate polyglutamate</td>
</tr>
<tr>
<td>NPF</td>
<td>National Psoriasis Foundation</td>
</tr>
<tr>
<td>NSAID</td>
<td>Nonsteroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>OSM</td>
<td>Oral small molecules—methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast</td>
</tr>
<tr>
<td>PASI</td>
<td>Psoriasis Area and Severity Index</td>
</tr>
<tr>
<td>PCV13</td>
<td>13-valent pneumococcal conjugate vaccine</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Definition</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>PDE4i</td>
<td>Phosphodiesterase 4 inhibitor</td>
</tr>
<tr>
<td>PGA</td>
<td>Patient Global Assessment</td>
</tr>
<tr>
<td>PPSV23</td>
<td>23-valent pneumococcal polysaccharide vaccine</td>
</tr>
<tr>
<td>PsA</td>
<td>Psoriatic arthritis</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RA</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>RCZ</td>
<td>Recombinant zoster (vaccine)</td>
</tr>
<tr>
<td>RF</td>
<td>Rheumatoid factor</td>
</tr>
<tr>
<td>SEAM-PsA</td>
<td>Study of Etanercept and Methotrexate in Combination or as Monotherapy in Subjects with Psoriatic Arthritis</td>
</tr>
<tr>
<td>SI</td>
<td>Sacroiliac</td>
</tr>
<tr>
<td>SLE</td>
<td>Systemic lupus erythematosus</td>
</tr>
<tr>
<td>SpA</td>
<td>Spondyloarthritis</td>
</tr>
<tr>
<td>SSA</td>
<td>Sjögren's-syndrome-related antigen A</td>
</tr>
<tr>
<td>SSB</td>
<td>Sjögren's-syndrome-related antigen B</td>
</tr>
<tr>
<td>T2T</td>
<td>Treat to target</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Tdap</td>
<td>Tetanus, diphtheria and pertussis (vaccine)</td>
</tr>
<tr>
<td>TNFi</td>
<td>Tumor necrosis factor inhibitor</td>
</tr>
<tr>
<td>tsDMARD</td>
<td>Targeted synthetic disease-modifying antirheumatic drug</td>
</tr>
<tr>
<td>UC</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>VAR</td>
<td>Varicella</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analog scale</td>
</tr>
<tr>
<td>VLDA</td>
<td>Very low disease activity</td>
</tr>
</tbody>
</table>
**Introduction**

In the United States (US), approximately 3% of the general population (5 million adults) have been diagnosed with psoriasis. Between .4% and 2.28% of the population is reported to have undiagnosed disease.\(^1\)

Psoriasis is a chronic inflammatory autoimmune disease of the skin, often presenting with patches of silvery scales on the skin and epidermal hyperplasia. Patients complain of dryness, itching, redness, soreness, and even pain in the affected areas. The skin overlying the elbows, knees, scalp, lower back, face, palms, and soles of the feet are the most commonly affected areas. Skin disease is often marked by unpredictable remissions and flares. Epidermal hyperplasia is a response to the activation of the immune system mediated by CD\(^8^+\) and CD\(^4^+\) T lymphocytes.\(^2\)

Psoriatic arthritis (PsA) is an autoimmune inflammatory arthritis that affects up to one third of the patients with psoriasis. It occurs equally in men and women between 30 and 50 years, and usually has a chronic progressive course. In addition to psoriasis, 80% to 87% of patients with PsA have concurrent psoriatic nail changes.\(^3\)\(^,\)\(^4\) The Toronto Psoriasis Cohort studied 464 patients with known psoriasis who had no evidence of PsA at the start of the study. However, in the course of the study (January 1, 2006 to September 5, 2014), 51 patients who developed PsA and nine additional patients who were suspected of developing PsA were lost to follow up. The annual incidence rate of PsA in this study was 2.7 per 100 cases of psoriasis. The authors also found that there was an increased risk for developing PsA in patients with psoriatic nail lesions, severe psoriasis, a history of systemic retinoid use, and uveitis.\(^5\) The majority of patients who develop PsA have a long history of psoriasis (up to 10 years prior to the development of PsA). In 15% of patients with PsA, psoriasis and PsA develop together; and in an additional 15%, PsA appears before the skin disease. Psoriatic arthritis is not commonly seen in African Americans or Asians.\(^6\)

A study published in the *Annals of Rheumatic Disease* reported on 402 patients with a diagnosis of either PsA or ankylosing spondylitis (AS) (201 patients in each arm of the study) to determine the incidence of overlapping disease.\(^7\) Both groups were tested for human leukocyte antigen-B27 (HLA-B27) and C-reactive protein (CRP). The authors concluded that there was overlap of the two diseases, especially in patients with PsA who tested positive for HLA-B27. This suggests that PsA with axial disease should be considered as part of a spectrum of disease between AS and PsA (see *United Rheumatology Clinical Practice Guideline—Axial Spondyloarthritis (SpA)*).

It is widely believed that both psoriasis and PsA are complex genetic autoimmune/autoinflammatory disorders; however, the heritability of either disease is not completely understood.\(^8\)
Psoriatic arthritis can involve one or more of the following domains:

- Peripheral arthritis
- Axial arthritis (SpA, AS)
- Enthesitis
- Dactylitis
- Skin
- Nails

It can be oligoarticular (≤4 joints) or polyarticular (≥5 joints) and may involve the distal interphalangeal (DIP) joints of the hands and feet only; or it may involve multiple joints, including the spine and sacroiliac (SI) joints. If the DIP joints are involved, nail changes are almost always present.

Psoriatic arthritis usually presents with joint pain and swelling, erythema, and warmth around the affected joint(s). Patients may also complain of joint stiffness or painful swelling and tenderness at the enthesis (bony insertion of ligaments, tendons, or joint capsules). Enthesitis (inflammation of the enthesis) most commonly occurs at the insertion of the plantar fascia, Achilles tendon, and around the elbow but can also be seen at the ligamentous attachments of the knees, ribs, spine, pelvis, and many other areas of the body. Dactylitis—a combination of enthesitis, tenosynovitis, and arthritis of all the joints of a single digit—is seen in up to 40% of patients with PsA. Clinically, when dactylitis is present, there is diffuse swelling of one or more digits.

Psoriatic arthritis is often (but not always) asymmetric in distribution, especially early on in the course of the disease. This can help distinguish PsA from rheumatoid arthritis (RA), which is more commonly symmetric and less likely to involve the DIP joints than PsA. The distinction between PsA and RA is based on clinical and laboratory data. In addition to the small joints of the hands and feet, large joints of the lower extremities, spine, SI joints, and pelvis may be affected by PsA. Approximately 40% of patients with PsA will have spinal or SI joint involvement (spondyloarthropathy) causing back pain and progressive ankylosis similar to AS. The majority of affected patients have peripheral PsA; only 5% have isolated axial PsA.

Sometimes, it is difficult to differentiate PsA from other rheumatic diseases, other types of arthritis, mechanical tendonitis, or fibromyalgia. Therefore, before treatment is started, it is essential that patients suspected of having PsA have a complete evaluation by a rheumatologist and, if there is significant skin involvement, a dermatologist as well. All PsA domains should be evaluated; including signs and symptoms of peripheral arthritis, skin psoriasis, enthesitis, dactylitis, axial joint disease (spondylitis or spondyloarthropathy, spine, and SI joints), and nail disease.

Psoriatic arthritis can be very disabling and negatively impact the quality of life (QoL) of those affected. In a 2005 report in the *Journal of the American Academy of Dermatology*, 39% of the patients with PsA indicated that the disease was a significant or large problem in their everyday lives; 38% believed that it was a problem; and only 23% reported that it was a small problem or no problem in daily life. Some patients with PsA are limited in their ability to perform activities of daily living, may be less productive at work, have increased absenteeism from work, and may be less likely to be employed than people without PsA. Patients may also suffer from decreased self-esteem and depression.
Psoriatic arthritis can be associated with comorbidities, including but not limited to Type 2 diabetes, hyperlipidemia, obesity, hypertension, and cardiovascular (CV) diseases such as myocardial infarction, congestive heart failure, cardiomyopathy, angina, and stroke. These comorbidities are seen more frequently in patients with PsA than in those with only involvement of the skin. In addition, there may be an increased incidence of liver and gastrointestinal (GI) diseases, fibromyalgia, autoimmune eye disease, as well as depression. In 2013, Husted et al. published a study of 631 patients with PsA and found that 42% had three or more comorbidities.

Data on the economics of caring for patients with PsA is not widely available. Some reports combine patients with psoriasis only with patients having psoriasis and PsA. Brezinski et al. published a systematic review of the overall costs of caring for patients with psoriasis and adjusted the base-year costs to 2013 dollars. They found that the direct costs were between $51.7 billion to $63.2 billion, with indirect costs ranging from $23.9 billion to $35.4 billion. Caring for comorbidities contributed another $36.4 billion in this study. Another study published in 2016 in the Journal of Managed Care compared 1230 patients with psoriasis and PsA to an equal number of patients with psoriasis without PsA (control group). The authors found that patients in the PsA group had more comorbidities, hospital admissions, emergency room visits, and outpatient visits than those in the control group. The overall 5-year cost of care was $23,150 more per patient in the PsA group than in the control group; pharmacy costs were $17,696 more per patient in the PsA group; and medical costs were $5077 greater per patient in this group.

In general, the earlier the diagnosis of PsA is established and treatment initiated the better the outcome. Individuals who smoke, are more than 50 years old, or have a history of a delay of 6 months or more since the onset of symptoms and diagnosis have a poorer outcome than young, nonsmoking patients who have been diagnosed earlier.

A 5-year follow-up study from the Swedish Early Psoriatic Arthritis Registry published in 2015 reported that men had a greater risk for bone erosions and structural damage than women. Interestingly, the study also found that, although men improved clinically, they developed more joint damage than women, who demonstrated less clinical improvement than men but had less joint damage. The authors suggest that men and women may need different treatment planning. Women may need more attention to pain control and physical function, whereas men, especially those with dactylitis, may need more intense radiographic follow-up.

**Diagnosis**

Currently there is no single test to definitively diagnose PsA. The diagnosis is established clinically using physical examination, blood tests and at times imaging.

The CASPAR (CIAsification criteria for Psoriatic Arthritis) criteria outlined below (Figure 1) are classification criteria used for entry into clinical trials. These criteria, published in 2006, are simple to use and have a sensitivity of 91.4% and specificity of 98.7%. Although they were initially designed for clinical trials and are not validated for use in a clinical setting, they are commonly used as diagnostic criteria in rheumatology practices.
Figure 1. CASPAR classification criteria for the diagnosis of PsA

CASPAR, CLAssification criteria for Psoriatic ARthritis; PsA, psoriatic arthritis
Adapted from Taylor WJ, et al.17.

Patient Assessment

As with other rheumatologic diseases, it is important to establish the diagnosis and initiate treatment as soon as possible.

Initial evaluation of a patient who meets the CASPAR classification criteria for PsA should include the following (other tests may be appropriate in certain clinical settings):

- Detailed medical history, including a detailed vaccination history
- Laboratory tests
  - Complete blood count (CBC)
  - CRP (elevated levels are seen in 40% of patients with PsA)8
  - ESR (elevated levels are seen in 40% of patients with PsA)8
  - HLA-B27 (positive in 25% of patients with PsA).8 If positive, there is an increased risk of axial disease and more aggressive course of disease.
  - Comprehensive metabolic panel (CMP)
Liver function
Renal function
  - Screening for hepatitis B (HBV) and hepatitis C (HCV)
  - Rheumatoid factor (RF) (negative in 95% of patients with PsA)
  - Anti-cyclic citrullinated protein antibodies (ACPA) (negative in 95% of patients with PsA)

Baseline radiographs of areas of clinical involvement. Radiographic changes include the following:
  - Peripheral joints—bone loss with joint space narrowing and eccentric erosions, periostitis, ankylosis, enthesophytes
  - Axial skeleton—sacroiliitis and vertical syndesmophytes
    - Bilateral sacroiliitis ≥Grade 2 (minimal changes, no narrowing of the joint space but with small erosions or sclerosis)
    - Unilateral sacroiliitis ≥Grade 3 (definitely abnormal with erosions and sclerosis on both sides of the joint; and widening, narrowing, or fusion of the joint)

Patient Global Assessment (PGA)
Patient pain visual analog scale (VAS) Multidimensional Health Assessment Questionnaire (MDHAQ; see Glossary)
Physician Global Assessment (MDG)
Number of tender joints
Number of swollen joints
If there is skin psoriasis, Psoriasis Area and Severity Index (PASI; see Glossary) or Body Surface Area (BSA) assessment

At this time, there is no confirmatory laboratory test to establish the diagnosis of PsA, but many patients test negative for RF (performed by any method other than latex fixation) and antinuclear antibodies (ANA), and some test positive for HLA-B27.

Active disease is diagnosed in patients (who have met the CASPAR classification criteria above) with any of the following:
  - ≥1 tender and inflamed joint(s)
  - ≥1 tender enthesis point(s)
  - ≥1 dactylitic digit(s)
  - Inflammatory back pain (IBP, see Glossary)

Patients are considered to have a poor prognosis if they have at least 1 of the following:
  - ≥5 actively inflamed joints
  - Elevated acute-phase reactants such as ESR or CRP
  - Imaging evidence of disease progression
  - Poor response to nonsteroidal anti-inflammatory drug (NSAID) therapy or prior use of steroids
  - Loss of function or diminished QoL
According to the 2018 American College of Rheumatology/National Psoriasis Foundation (ACR/NPF) Guideline for the Treatment of Psoriatic Arthritis,21 a patient with one or more of the following has severe PsA:

- Bone erosions
- Elevated acute-phase reactants (CRP, ESR) due to PsA
- Joint deformities that interfere with function
- Impairment of QoL
- Active PsA at multiple sites, which may include enthesitis and/or dactylitis
- Rapidly progressive disease
- Function-limiting PsA at a number of sites

In addition, the ACR/NPF Guideline states that severe psoriatic skin disease is defined as one or more of the following:21

- Psoriasis Area and Severity Index (PASI) of ≥12
- Body Surface Area (BSA) of ≥5% to 10%
- Involvement of face, nails, scalp, feet, and hands
- Physical or mental impairment

**Management of Patients with PsA**

The management of patients with PsA should be based on a treat-to-target (T2T) paradigm, with therapy aimed at achieving remission or minimal disease activity (MDA, see below) as quickly as possible.22 Some authors have proposed the more stringent criteria for very low disease activity (VLDA), which are closer to remission.23

As Ritchlin et al.6 recommended in their 2017 article, “The domain with the highest level of activity drives the treatment choices” (Page 966). If there is psoriatic skin disease, coordination of treatment with a dermatologist is strongly encouraged. Regular close monitoring and re-evaluation of therapy are essential to maintaining stability of this disease, avoiding medication toxicity, and identifying comorbid conditions early.

Remission is defined as no evidence of active disease (see Patient Assessment, above). To achieve MDA, the patient must meet five of the following seven conditions; to achieve VLDA, the patient must meet all seven:24

1. Tender joints ≤1
2. Swollen joints ≤1
3. Pain VAS ≤15
4. Patient Global Assessment ≤20
5. MDHAQ ≤.5
6. PASI <1 or BSA ≤3
7. Tender enthesal points ≤1
In the study by van Mens et al., VLDA was reached by fewer patients than MDA. The authors felt that VLDA was closer to remission than MDA. However, they cautioned that VLDA may be too stringent and achievement of this very low level of disease would be difficult for many patients. It has yet to be determined if the course of the disease is better for those at VLDA compared to those at MDA. It is also unknown at this time whether achieving VLDA results in overtreatment of patients and increased adverse reactions to medications.

Radiographic progression can be defined as an increase in Sharp/van der Heijde scores of the hands and feet of >0.24. Comorbidities must be considered as well when developing a treatment plan. These include but are not limited to:

- Uveitis
- Inflammatory bowel disease (IBD)
- CVD
- Obesity, metabolic syndrome
- Diabetes
- Depression and anxiety
- Chronic hepatitis
- Non-alcoholic fatty liver disease, cirrhosis
- Hypertension
- Chronic alcohol abuse
- Renal disease
- Malignancies, including skin cancer
- Osteoporosis
- Central sensitization syndrome (fibromyalgia)
- Interstitial lung disease
- Recurrent or increased susceptibility to infections
- Crohn’s disease and subclinical colitis

Patients with comorbidities should be referred to the appropriate medical specialist for management.

Due to dysregulated immune function and exposure to immunomodulating medications, patients with PsA have an increased risk of infection. Prior to starting therapy, it is important to obtain a detailed vaccination history. Providers should assess the need for a variety of vaccinations according to the Centers for Disease Control and Prevention (CDC) schedule which include the following:

- Annual flu vaccine
- PCV13 (13-valent pneumococcal conjugate vaccine)—one dose if not previously administered followed by one dose of PPSV23 (23-valent pneumococcal polysaccharide vaccine) at least 1 year after the PCV13 vaccination
- Recombinant zoster (RCZ) vaccine for adults 50 years of age and older—2 doses
- Human papillomavirus (HPV) vaccine—2 or 3 doses for patients up to age 26
- Hepatitis A vaccine—2 to 3 doses if antibody negative
- Hepatitis B vaccine—3 doses if antibody negative
- Tdap (tetanus, diphtheria, and pertussis) vaccine—1 dose followed by a booster every 10 years

The 2018 ACR Guideline indicates that biologics should not be delayed if killed vaccines are used. However, if live attenuated vaccines are used then biologics should be delayed.21
Patients over age 50 years should receive a herpes zoster vaccination, if not previously done. Currently, there are two herpes zoster vaccines available: Zostavax®, which contains live virus and is considered to be contraindicated by the CDC for this population, and Shingrix® (currently in very short supply in the US), which contains a non-live subunit of the virus. Shingrix is reported to be 97% effective against shingles when compared to Zostavax, which is 51% effective against herpes zoster. If patients have active PsA requiring treatment, Shingrix is the vaccine of choice because not only is it more effective but also avoids delaying the start of treatment. If Shingrix is not available and a patient has active PsA, Zostavax may be given but pharmacologic treatment for PsA should be delayed for 2 to 4 weeks after the vaccination.21

According to the CDC, MMR (mumps, measles and rubella) vaccine and VAR (varicella) vaccine are contraindicated in immunocompromised patients.

The date and result of the most recent tuberculosis (TB) evaluation should be documented and the patient re-screened annually. A travel history to areas where certain fungal diseases are prevalent is also important.

Management should always be directed by a rheumatologist or under the supervision of a rheumatologist. Psoriatic arthritis is a very heterogenous disease and one or more domains (peripheral arthritis, axial arthritis, dactylitis, enthesitis, skin psoriasis, or psoriatic nail dystrophy) may be involved at the same time. The provider should choose a treatment plan that takes into account as many of the involved domains as possible.27 Treatment should also be adjusted if the established target is not reached within the expected timeframe.

Nonpharmacologic Treatment

Nonpharmacologic treatments should be part of every patient’s treatment plan, if possible. These include low-impact exercise such as swimming, yoga, and Tai Chi; physical and/or occupational therapy; massage therapy; and acupuncture. Some patients may prefer high-impact exercises.21 In addition, patients should be strongly encouraged to stop smoking and lose weight.

Pharmacologic Management

Psoriatic arthritis is a heterogeneous disease, and different drugs are preferred for the management of different domains. Patients commonly have more than one domain involved. When developing a pharmacologic treatment plan, it is important to consider all of the involved domains,27 the severity of the disease, the presence of poor prognostic factors, comorbidities, and the patients’ preferences. Treatment should be planned based on the most dominant domain.

Rheumatology providers should coordinate care with the patient’s dermatologist and primary care provider, in addition to other medical specialists when appropriate. All patients should have an annual total body skin screening for non-melanoma skin cancers by a dermatologist.

Continuous monitoring of a patient’s response to treatment is important as it may reveal inadequate disease control indicating a need for modification or change in drug management.
Pharmacologic treatment should be started as soon as possible after the diagnosis is confirmed. The goal of treatment should be either a complete remission or minimal disease activity (MDA).

Table 1 lists drugs used for the pharmacologic management of patients with PsA.

Table 1. Drugs used for the pharmacologic management of PsA

<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>Oral</td>
<td>GI bleeding, history of gastric ulcers, congestive heart failure, cirrhosis, renal disease²⁸</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>Oral, IA, or rarely IV</td>
<td></td>
</tr>
<tr>
<td>csDMARDs/OSM*</td>
<td>Oral</td>
<td>Alcoholism, alcoholic liver disease, other chronic liver disease; pre-existing blood dyscrasias, known allergy to MTX, planning for pregnancy²⁹</td>
</tr>
<tr>
<td>Methotrexate (Rheumatrex® or generic)</td>
<td>Oral</td>
<td>Alcoholism, alcoholic liver disease, other chronic liver disease; pre-existing blood dyscrasias, known allergy to MTX, planning for pregnancy³⁰</td>
</tr>
<tr>
<td>Methotrexate (Otrexup™ or Rasuvo® or generic)</td>
<td>SQ</td>
<td>Alcoholism, alcoholic liver disease, other chronic liver disease; pre-existing blood dyscrasias, known allergy to MTX, planning for pregnancy³⁰</td>
</tr>
<tr>
<td>Leflunomide (Arava®)</td>
<td>Oral</td>
<td>Alcoholism, alcoholic liver disease, other chronic liver disease, pre-existing blood dyscrasias, severe skin psoriasis</td>
</tr>
<tr>
<td>Sulfasalazine (Azulfidine®)</td>
<td>Oral</td>
<td>Allergy to sulfa, leucopenia</td>
</tr>
</tbody>
</table>

²⁸ Renal failure may occur in patients with severe psoriasis.
²⁹ Alcoholism, liver disease, or other chronic liver disease; pre-existing blood dyscrasias; known allergy to MTX; planning for pregnancy.
³⁰ Alcoholism, liver disease, or other chronic liver disease; pre-existing blood dyscrasias; known allergy to MTX; planning for pregnancy.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Route of Administration</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>boDMARDs</strong></td>
<td></td>
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<tr>
<td><strong>TNFi</strong></td>
<td></td>
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<tr>
<td>Infliximab-qbtx (Remicade®)</td>
<td>IV</td>
<td></td>
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<tr>
<td>Etanercept (Enbrel®)</td>
<td>SQ</td>
<td></td>
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<tr>
<td>Adalimumab (Humira®)</td>
<td>SQ and IV</td>
<td></td>
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<tr>
<td>Golimumab (Simponi®)</td>
<td>SQ</td>
<td></td>
</tr>
<tr>
<td>Golimumab (Simponi® Aria)</td>
<td>IV</td>
<td></td>
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<tr>
<td>Certolizumab pegol (Cimzia®)</td>
<td>IV or SQ</td>
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<tr>
<td><strong>IL-12/23i</strong></td>
<td></td>
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<tr>
<td>Ustekinumab (Stelara®)</td>
<td>SQ</td>
<td></td>
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<tr>
<td><strong>IL-17i</strong></td>
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<tr>
<td>Secukinumab (Cosentyx®)</td>
<td>SQ</td>
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</tr>
<tr>
<td>Ixekizumab (Taltz®)</td>
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<td></td>
</tr>
<tr>
<td><strong>T cell costimulation inhibitor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abatacept (Orencia®)</td>
<td>IV or SQ</td>
<td></td>
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<tr>
<td><strong>bsDMARDs</strong></td>
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<td>Erelzi (originator drug: etanercept-szsz [Enbrel])</td>
<td>SQ</td>
<td>Same as for bo DMARDs</td>
</tr>
<tr>
<td>Amjevita** (originator drug: adalimumab [Humira])</td>
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<td>IV</td>
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<td>Renflexis (reference drug infliximab-qbtx [Remicade])</td>
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<td></td>
</tr>
<tr>
<td>Cyltezo (reference drug adalimumab-adbm [Humira])</td>
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<tr>
<td>Hyrimoz (reference drug adalimumab-adaz)</td>
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<tr>
<td><strong>tsDMARD</strong></td>
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<tr>
<td>Tofacitinib (Xeljanz®) (JAKi)</td>
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<td><strong>PDE4i/OSM</strong></td>
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<tr>
<td>Apremilast (Otezla®)</td>
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<td>Drug</td>
<td>Route of Administration</td>
<td>Contraindications</td>
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</tr>
<tr>
<td>Cyclosporin</td>
<td>Oral</td>
<td>• Not to be used for more than 1 year</td>
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<tr>
<td></td>
<td></td>
<td>• Do not use if:</td>
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<td></td>
<td></td>
<td>o Compromised immune system</td>
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<td>o Severe gout</td>
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<td>o Abnormal renal function</td>
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<td></td>
<td></td>
<td>o Hypertension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>o History of cancer other than basal cell or squamous cell of the skin</td>
</tr>
</tbody>
</table>

*TThere is no role for csDMARDs in the management of patients whose only complaint is axial PsA or enthesitis.*

Tumor necrosis factor inhibitors (TNFi) are the most frequently used drugs for the management of patients with severe skin disease, severe PsA, axial PsA, enthesitis, dactylitis, and concomitant IBD. These drugs are divided into three categories: monoclonal antibodies, soluble fusion molecules, or neither. The drugs are classified below:21, 33-36

- Monoclonal antibodies
  - Infliximab-qbtx (Remicade®)
  - Adalimumab (Humira®)
  - Golimumab (Simponi®)
  - Golimumab (Simponi® Aria)

- Monoclonal antibody fragment
  - Certolizumab pegol (Cimzia®)

- Soluble fusion molecule
  - Etanercept (Enbrel®)

Not all TNFi drugs can be used for the same indications. For example, soluble fusion molecules should not be used in patients with IBD.
Patients with PsA often have multiple comorbidities which must be considered when deciding if a TNFi medication should be used. The contraindications for the use of these drugs include but are not limited to: 21, 37

- Current infection
- History of recurrent or chronic infections
- Untreated tuberculosis (active or latent)
- Moderate to severe congestive heart failure (CHF)
- Multiple sclerosis or other demyelinating diseases
- Optic neuritis

Peripheral Arthritis

Guidelines from national and international rheumatology specialty organizations are inconsistent with one another regarding the use of methotrexate for patients with PsA that involves peripheral joints only. There is very little data to support using methotrexate as an initial option. The Study of Etanercept and Methotrexate in Combination or as Monotherapy in Subjects with Psoriatic Arthritis (SEAM-PsA) evaluating treatment-naive patients with PsA showed greater improvement with a TNFi drug in this population; it also demonstrated the efficacy of methotrexate alone but without placebo control. 38 The European League Against Rheumatism (EULAR) recommends methotrexate as the initial drug for the treatment of patients with peripheral arthritis only. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) rates the csDMARDs (methotrexate, leflunomide, sulfasalazine) or oral small molecules (OSM, which include the csDMARDs and apremilast), and TNFi drugs as strongly recommended for the management of peripheral arthritis for this same population. However, GRAPPA also indicates that csDMARDs (the ones listed above) should be used first. The new ACR Guideline indicates that methotrexate is an option for this population, but that TNFi drugs are their first choice, unless contraindicated. 19, 21, 39

For DMARD-naïve patients with **peripheral joint involvement only (no evidence of axial disease, enthesal involvement, dactylitis, severe skin disease, or previously defined severe PsA) and no evidence of poor prognostic factors**, United Rheumatology recommends a trial of an OSM for 3 months (Figure 2).

If methotrexate is chosen as the initial OSM it should be started at 10 mg to 15 mg per week orally and the dose escalated up to a maximum of 25 mg per week depending on the patient’s response. At doses of 15 mg per week or more, split dosing should strongly be considered (the total dose is divided into two separate doses taken 8 hours apart). At 20 mg per week, some providers switch to subcutaneous methotrexate. 40 At this dose, there is better absorption of the drug subcutaneously than orally. If either methotrexate or leflunomide are contraindicated, a phosphodiesterase 4 inhibitor (PDE4i, apremilast) can be tried, taking into consideration any history of depression. Apremilast or sulfasalazine should also be used if the patient has a history of uncontrolled diabetes. Leflunomide or sulfasalazine should not be chosen if there is more than mild skin involvement. At the end of 12 weeks, if the patient is in remission
or has reached MDA with an OSM, then treatment should be continued with the same drug at the same
dose and the patient monitored carefully to ensure that there is no change in disease activity. If at the
end of 3 months, the patient has not reached remission or MDA with an OSM, then a biologic should be
tried. Monotherapy with a TNFi drug or monotherapy with an interleukin-17 inhibitor (IL-17i) is preferred,
but a targeted synthetic (tsDMARD) or a T cell costimulation inhibitor can be considered when skin
involvement is mild. Interleukin-12/23 drugs should be considered if the patient has IBD or prefers less
frequent administration of medications. Targeted synthetic DMARDs should be considered if the patient
has ulcerative colitis (UC), Candida infections or prefers an oral medication. A T cell costimulation inhibitor
can be considered, if the patient has recurrent or serious infections, or a demyelinating disease such as
but not limited to multiple sclerosis (Figure 2).21

Patients with poor prognostic factors and/or severe skin disease and/or severe PsA with no axial disease
and/or no enthesal disease and/or no dactylitis should be started on a biologic originator/biosimilar
disease-modifying antirheumatic drugs (bo/bs DMARD) initially (Figure 3). Selection should be based on
all domains involved and all comorbidities. If there is significant skin involvement, abatacept or a Janus
Kinase inhibitor (JAKi) drug should not be the first or second choice. For more significant arthritis, a TNFi
or IL-17i should be the first choice. If there is active spondylitis only, a TNFi or IL-17i should be chosen.
Use of a monoclonal type TNFi or an IL-12/23i drug should be considered, if the patient has IBD or a drug
that is given less often is preferred. A JAKi drug can be considered, if the patient has a history of UC or
recurrent Candida infections, or prefers an oral medication. A T cell costimulation inhibitor such as
abatacept can be considered, if there is a history of recurrent or serious infections and/or demyelinating
disease, or stable IBD.21

If the patient achieves remission or MDA after 3 months on the initial therapy, then the current treatment
should be continued. If neither remission or MDA is reached, then a different bo/bs or tsDMARD should
be started (Figure 3).21
Figure 2. Initial treatment of patient with peripheral PsA and no evidence of axial disease, enthesitis or dactylitis.

Note: Please see text for additional information about the drug classifications and contraindications.

boDMARD, biologic disease-modifying antirheumatic drug; bsDMARD, biosimilar disease-modifying antirheumatic drug; MDA, minimal disease activity; MTX, methotrexate; OSM, oral small molecule; PsA, psoriatic arthritis; TNFi, tumor necrosis factor inhibitor; tsDMARD, targeted synthetic disease-modifying antirheumatic drug
Figure 3. Management PsA with no evidence of axial disease, enthesitis or dactylitis and presence of either poor prognostic factors, and/or severe PsA and/or severe skin disease

Note: Please see text for additional information about the drug classifications and contraindications.

IL-17i, interleukin-17 inhibitor; IL-12/23, interleukin-12/23 inhibitor; JAKi, Janus Kinase inhibitor; MDA, minimal disease activity; PsA, psoriatic arthritis; TNFi, tumor necrosis factor inhibitor; tsDMARD, targeted synthetic disease-modifying antirheumatic drug
Axial PsA (Spondylitis or Spondyloarthropathy and Sacroiliitis)

Axial disease rarely occurs alone; it frequently occurs in combination with peripheral PsA. Clinical findings of IBP or imaging findings of sacroiliitis establish the diagnosis of axial disease. Initial treatment for mild or stable disease should begin with nonsteroidal anti-inflammatory drugs (NSAIDs) given on a continuous schedule and not on an as-needed basis. Physical therapy should also be initiated. Systemic treatment with glucocorticoids should be avoided. Sacroiliac joint injections of steroids can be considered in appropriate situations. Conventional synthetic DMARDs, IL 12/23 inhibitors, and PDE4i inhibitors are not indicated for the treatment of patients with axial PsA or for those with a combination of peripheral joint arthritis and axial disease. For patients failing to respond to NSAIDs, a TNFi or IL-17i drug should be used as the initial biologic originator disease-modifying antirheumatic drug (boDMARD). If the patient fails to respond to the initial boDMARD (TNFi or IL-17i), a different TNFi or IL-17i should be tried until the clinical target is reached.

If there is a contraindication to TNFi drugs or the patient has severe skin disease in addition to axial PsA (with or without peripheral PsA), an IL-17i drug should be used (Figure 4).
Figure 4. Axial PsA (dominant domain)

Note: Please see text (Axial PsA) for additional information. All medication decisions must take into account the patient’s complete medical history, including but not limited to adverse events related to drugs, skin disease, IBD, and other comorbidities. IBD, inflammatory bowel disease; IL-17i, interleukin-17 inhibitor; MDA, minimal disease activity; NSAIDs, nonsteroidal anti-inflammatory drugs; PsA, psoriatic arthritis; TNFi, tumor necrosis factor inhibitor.
Enthesitis

An enthesis is the area where a tendon or ligament inserts into a bone. Inflammation at the enthesis is quite common in PsA, affecting up to half of the patients. This often occurs at the insertion of tendons or ligaments such as the Achilles’ tendon, the plantar fascia, and ligaments and tendon insertions at the lateral epicondyles. It may also be seen in the vertebrae of patients with axial PsA. In fact, enthesitis and/or dactylitis may be the initial presenting complaint(s) or symptom(s). Ultrasound has been found to be a good imaging test for enthesitis.

Physical therapy should be started. Local steroid injections should be used with extreme caution, because data suggest potential structural damage and rupture of the enthesis. The patella and Achilles tendons should not be injected. Conventional synthetic DMARDs are not recommended for patients whose main domain of involvement is enthesitis. The patient should be started on NSAIDs initially. If there is an inadequate response to NSAIDs, the patient should be started on either a TNFi, IL-17i, IL-12/23i, or a tsDMARD. If the patient fails to respond to the first DMARD, then she/he can be switched to another TNFi or, if not already tried, to an IL1-7i, IL12/23i, or a tsDMARD until remission or MDA is reached. If the second DMARD fails to achieve remission or MDA, then a different drug from the group mentioned above should be tried until remission or MDA is achieved.

For patients with contraindications to bo/cs DMARDs and a history of recurrent infections or for those who prefer an oral medication, a PDE4i drug (apremilast) can be used. For patients for whom NSAIDs are contraindicated and who do not have either severe skin disease and/or severe PsA, a PDE4i drug such as apremilast may be used as the initial drug. In this group, if there is no remission or MDA with apremilast, then a bo/cs DMARD or tsDMARD should be tried. If the patient has a contraindication to a TNFi or severe skin disease, then an IL-17i or IL-12/23i drug should be tried. If the patient has a history of IBD, then an IL-12/23i drug can be used (see Figure 5).
Figure 5. Enthesitis (dominant domain)

Note: Please see text (Enthesitis) for additional information. All medication decisions must take into account the patient’s complete medical history, including but not limited to adverse events related to drugs, skin disease, IBD, and other comorbidities.

bo/bS DMARD, biologic originator/biosimilar disease-modifying antirheumatic drug; IBD, inflammatory bowel disease; MDA, minimal disease activity; NSAIDs, nonsteroidal anti-inflammatory drugs; PDE4i, phosphodiesterase 4 inhibitor; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.
Dactylitis

Dactylitis, commonly called ‘sausage digit’, describes inflammation of an entire digit with diffuse swelling, pain, and tenderness of the digit and is frequently associated with progressive disease. Unfortunately, there is only weak evidence supporting the use of any specific drug for this domain.

Patients with dactylitis should receive a trial of a boDMARD of the TNFi or IL-17i class, or IL-12/23i, tsDMARD (tofacitinib), or PDE4i (apremilast). If the patient has severe skin disease, the IL-17i class should be chosen. If there are recurrent infections, PDE4i (apremilast) should be utilized (Figure 6).
Figure 6. Dactylitis (dominant domain)

Note: Please see text (Dactylitis) for additional information. All medication decisions must take into account the patient’s complete medical history, including but not limited to adverse events related to drugs, skin disease, IBD, and other comorbidities.

IBD, inflammatory bowel disease; IL-17i, interleukin-17 inhibitor; MDA, minimal disease activity; PDE4i, phosphodiesterase 4 inhibitor; TNFi, tumor necrosis factor inhibitor; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.
Active PsA and Inflammatory Bowel Disease Together

For patients with active PsA and IBD who are treatment-naïve, the initial drug of choice should be a monoclonal antibody TNFi drug (infliximab, adalimumab, or golimumab). Etanercept is a fusion molecule and should not be used for these patients. In addition, IL-17i drugs should be avoided in patients with IBD. If the first TNFi monoclonal antibody does not have an adequate response, the patient should be started on a different TNFi monoclonal antibody until the desired result is achieved. If the patient fails to reach the desired target using TNFi monoclonal antibodies and if the patient has Crohn’s disease, an IL-12/23i drug should be tried; if the patient has UC, a tsDMARD should be tried (Figure 7).
Figure 7. Active PsA and inflammatory bowel disease

Note: Please see text (Active PsA and Inflammatory Bowel Disease Together) for additional information. All medication decisions must take into account the patient’s complete medical history, including but not limited to adverse events related to drugs, skin disease, inflammatory bowel disease, and other comorbidities. Etanercept is a fusion molecule TNFi agent that should not be used in patients with inflammatory bowel disease; IL-17i drugs should also be avoided in patients with IBD.

IBD, inflammatory bowel disease; IL-12/23i, interleukin-12/23 inhibitor; IL-17i, interleukin-17 inhibitor; MDA, minimal disease activity; PsA, psoriatic arthritis; TNFi, tumor necrosis factor inhibitor; tsDMARD, targeted synthetic disease-modifying antirheumatic drug.
Monitoring

When caring for a patient with PsA, clinicians must have a treatment target—either remission or MDA. In clinical practice, fewer patients achieve and maintain remission than MDA.

Once patients have started therapy, they should be seen at 4- to 6-week intervals until the disease is stable and as close to target as possible. At that point, they should be seen as appropriate. An MDA score should be measured at every visit, and medications should be adjusted as appropriate. Once patients have achieved MDA, they can be seen every 6 months, with disease measurements obtained at each visit. Any patient experiencing a change in symptoms or functional ability should be seen as soon as possible. Monitoring of blood tests should be performed at regular intervals, as clinically appropriate. It is suggested that X-rays should also be repeated as clinically appropriate. Tuberculosis testing should be done annually.

Patients who are taking methotrexate should have repeat liver function tests (LFTs) at least once during the first 3 months of treatment. Those who continue on the drug should have LFTs along with renal function tests every 6 months. All blood tests should be drawn at least 5 days after the last dose of methotrexate.45

For patients on TNFi drugs, blood tests should be done prior to starting treatment and should include a CBC, liver and renal function tests, and electrolytes. Four weeks after starting therapy; the CBC, liver and renal function tests, and electrolytes should be repeated. At 3 months, the blood tests should be repeated. If the results are stable, the tests should be repeated every 3 to 6 months.45

Women’s Reproductive Health and Psoriatic Arthritis

Approximately half of the patients with PsA are women, and they are often diagnosed during their childbearing years. During the last 2 decades, many medications have been introduced to treat PsA. These new drugs can result in good disease control for many of these young women who, in the past, were either not adequately controlled or felt too ill to consider childbearing. With the introduction of these more effective drugs, women have an improved QoL and are more likely to consider childbearing.

Very early in the relationship between a woman of reproductive age and her healthcare provider(s), it is important to understand her future plans for a family and to discuss the importance of integrating her PsA treatment into her program for family planning.46 Regardless of whether or not a patient wants to have children, it is important to discuss the risks of an unintended pregnancy. Half of the pregnancies in the US are unplanned. If the patient wishes to avoid a future pregnancy, referral to her gynecologist or primary care physician for effective family planning is necessary (if she does not yet have a reliable plan with an obstetrician/gynecologist or primary care physician). Some women may wish to become pregnant very soon after the diagnosis of PsA or in the not too distant future. These patients also benefit from referral to their obstetrician/gynecologist to discuss and start an effective program of family planning. It is very important to impress upon the patient that her PsA and any associated comorbidities must be well controlled prior to conception to achieve the best possible pregnancy outcome. If there is an unplanned pregnancy, the patient should be instructed to contact her rheumatologist immediately.
Patients planning for a pregnancy must avoid any medications that could be harmful to a fetus for at least 3 to 6 months prior to conception and for the entire pregnancy. Management of these patients requires close collaboration between the patient’s rheumatologist, dermatologist, primary care physician, and obstetrician (or maternal fetal specialist) for the best pregnancy outcome. It is also important that comorbidities such as diabetes, metabolic syndrome, high blood pressure, renal disease, chronic alcohol abuse, malignancies including skin cancers, interstitial lung disease, obesity and CV disease are well controlled before these women conceive.

In 2014 and 2018, the ACR published information about rheumatic diseases and pregnancy which included the following recommendations:47

- Rheumatic/autoimmune diseases should be controlled for at least 3 to 6 months before trying to conceive.
- Patients can stay on their medications if they are safe for a fetus but this should be discussed with both the patient’s rheumatologist and obstetrician. No changes in medications used to treat rheumatic/autoimmune diseases should be made by any treating physician without the approval of the patient’s rheumatologist.
- Women with known pulmonary hypertension are advised not to become pregnant because the underlying lung disease may worsen during pregnancy.

Once a patient’s PsA is under control for at least 3 to 6 months, she may consider planning for a pregnancy. Drugs that decrease fertility or can cause congenital anomalies, fetal death, or spontaneous abortions during pregnancy should not be taken during this time and they should not be taken during pregnancy. However, in some cases it may be necessary for a woman with PsA to take some medication(s) to control her disease and prevent or limit long-term disability. Medication choices should be discussed with the patient, and she and her physician(s) should decide which medication(s) is/are most appropriate for her (Table 2).46

Contraception

Selection of the most effective and appropriate contraception should be a decision that is reached jointly by the patient and her physician(s).

Most of the information about contraception for patients with rheumatic/autoimmune diseases comes from studies of patients with RA, SLE, and IBD. According to Mitchell et al.,48 most forms of birth control are safe for women with rheumatic/autoimmune disorders. These include barrier methods, intrauterine devices (IUDs), and hormonal contraception.49 However, this may not apply to women with SLE (please refer to United Rheumatology Clinical Practice Guidelines—Systemic Lupus Erythematosus).

Multiple different IUDs are available. The pros and cons of each device should be discussed with the patient if she chooses this method. Some of the issues to be considered for IUDs include potential pregnancy as well as changes in menstrual flow, dysmenorrhea, expulsion, and a risk of infection, which is especially important in a patient who may be on immunosuppressive therapy. However, according to Sammaritano et al.,49 there is insufficient data to support a concern for infection.
Oral contraception (birth control pills) usually contain a combination of estrogen and progesterone. Transdermal patches, which also usually contain a combination of estrogen and progestin, can be used as well. In a study published in 2001, adherence to the patch was reported to be better than to oral contraceptives. Subdermal implants using progestin only are considered to be the most effective form of hormonal contraception. Other possible forms of hormonal contraception include a vaginal ring or injections of depot medroxyprogesterone acetate (DMPA), which are given every 3 months by either the patient or her provider. Barrier methods such as male and female condoms, diaphragms, and cervical caps are among the least effective methods of contraception.

It is important to remember that any contraceptive containing estrogen is not safe for women who test positive for anti-phospholipid antibodies.

No method is foolproof; therefore, patients must be counseled about the risks of unplanned pregnancies as mentioned above. In addition, the individual patient’s medical condition, including autoimmune diseases and comorbidities, must be taken into consideration when deciding on an appropriate plan for contraception.

**Pregnancy**

A pregnancy is considered to be high-risk, if the mother has any of the following medical problems:

- Preterm labor
- Preeclampsia
- Placental problems
- Twins or other multiples
- Diabetes
- Hypertension
- Renal disease
- Epilepsy
- Problems in a prior pregnancy including but not limited to genetic abnormalities of the baby
- History of multiple miscarriages
- Fetal heart, lung or kidney problems in a prior pregnancy
- HIV or HCV, cytomegalovirus, chicken pox, rubella, toxoplasmosis, syphilis
- Sickle cell anemia
- Asthma
- Autoimmune disease such as systemic lupus erythematosus, RA, or AS
- Antiphospholipid syndrome
- Age of mother at delivery of ≥35 years, or adolescents
- Thyroid disease
- Obesity
• Zika infection
• Alcohol use
• Smoking
• Substance abuse

Pregnancy in women with a rheumatic/autoimmune disease(s) is always considered to be high-risk; however, additional problems can further increase their risk. These include but are not limited to:

• Flare of known rheumatic/autoimmune disease
• History of prior blood clots
• *In vitro* fertilization (IVF)
• Presence of either Sjögren’s-syndrome-related antigen A (SSA) and/or Sjögren’s-syndrome-related antigen B (SSB) antibodies

As stated above, it is important that women have their disease and comorbidities under good control before conception. This may require the use of medications as not all patients can be adequately controlled without drugs. The Food and Drug Administration (FDA) has not designated any medication used to manage patients with PsA as safe for use in pregnancy. The physician and patient should carefully review the safety profile of the appropriate drugs and together determine which one is best for that patient.

Placental transfer of certolizumab pegol (Cimzia), a TNFi, was studied prospectively in the CRIB study of 16 pregnant women all of whom had a rheumatic disorder and were 30 or more weeks pregnant. Two neonates were not included in the final analysis, because they did not meet the study protocol. The drug was not detectable in 13 neonates at birth, and one had minimally detectable levels of the drug (.09% of the level detected in the mother). All of the mothers had the expected blood levels of the drug at delivery. Three infants had very low level of certolizumab pegol detected in cord blood. The drug was not detectable in the infants at 4 and 8 weeks after delivery. With no to minimal transfer of certolizumab pegol to the infants detected, the study concluded that treatment with certolizumab pegol was compatible with pregnancy.

According to the British Society for Rheumatology and the British Health Professionals in Rheumatology guidelines, TNFi drugs can be used in pregnancy but with caution. EULAR indicates that the csDMARDs sulfasalazine and hydroxychloroquine are “compatible” with pregnancy. The systematic review published by EULAR indicates that TNFi drugs should be considered to control disease activity in the “first part of pregnancy” (Page 797) and that only etanercept and certolizumab pegol can be considered for use throughout pregnancy because only very small amounts of these drugs are transported across the placenta. This is consistent with the recommendations above from the British Society of Rheumatology. According to EULAR other biologics such as rituximab, abatacept, and to felvizumab should only be used when no other safer drug can control the mother’s disease (Table 2).
In 2017, Polachek et al. published a retrospective report on patients with PsA who were pregnant between 1990 and 2015. The study group included 29 women with PsA who had 42 pregnancies during the study period. Forty of the pregnancies resulted in a live birth. Disease activity in 58.5% of the pregnancies either improved or was stable at low disease activity. In the postpartum period 52.5% either improved or had stable low disease activity, 40% had worsening or stable high disease activity.

Berman et al., published a retrospective review of disease activity of 25 pregnant women with PsA. The 25 women had 35 pregnancies with 33 live births. Only the 33 live births were included in the study. Twenty-one of these patients had been treated with biologics before conception. Fifteen women in this group stopped biologics close to conception or in the first trimester. Five of the 15 had mild to severe disease prior to conception. Over the course of the pregnancy and the first year postpartum 14 of these 15 women developed mild to severe disease, whereas in the 6 women who had stayed on biologics throughout the course of their pregnancy, disease activity was unchanged. The authors indicate that maintaining patients on biologics while pregnant decreased the incidence of pregnancy flares and postpartum flares. Those women who were never treated with biologics either before, during or in the one year following delivery, disease activity tended to improve during pregnancy but worsen in the postpartum period.

Women with psoriasis were reported to have a higher rate of spontaneous abortions when compared to women without psoriasis. They were also reported to have an increased risk of:

- High blood pressure
- Pre-eclampsia
- Premature rupture of membranes
- Gestational diabetes
- Elective and emergency caesarean section
- Neonatal macrosomia
- Low birthweight
- Babies that are large for gestational age

There is very little in the literature regarding pregnancy outcomes of women with PsA. There is a more information about pregnancy outcomes in women with RA and IBD (Crohn’s disease and ulcerative colitis). Much of the information is based on small studies and, in general, the changes reported during pregnancy were inconsistent.

Methotrexate and leflunomide are contraindicated before conception and during pregnancy (Table 2). Another paper found that discontinuing TNFi drugs early in pregnancy increased the risk for flares. Patients should be cautioned about the use of NSAIDs while trying to conceive and during pregnancy. In 2003, Li et al. published a report on the effects of NSAIDs on pregnancy. The patients in this study did not have PsA or any other inflammatory arthritis or autoimmune disease. The authors reported that if NSAIDs were used early in pregnancy (especially near the time of conception) or for more than 1 week the risk of miscarriage was increased. The risk for miscarriage was reported to be 10% for any NSAID use; 35% for use near conception, and 52% for more than 1 week of use. In a more recent study, researchers confirmed that women who had used NSAIDs around conception had a greater risk for miscarriage than
those who had not used NSAIDs. The association of NSAIDs with miscarriage was stronger for women who had a low body mass index. The risk of miscarriage increased along with increasing exposure to NSAIDs during pregnancy. None of the women in this study were reported to have an inflammatory arthritis or autoimmune disease.  

Nonsteroidal anti-inflammatory drugs should not be taken in the third trimester because of their association with stenosis of the ductus arteriosus in late pregnancy.

Lactation

There is very limited information regarding nursing mothers with PsA and medication safety. Healthcare providers should refer to the section below, Medications Used to Treat PsA and their Potential Effects on Pregnancy and Lactation. The decision to use any drug during lactation is one that should be made by the patient and her provider(s) together, based on their current understanding of the drug, including but not limited to the amount of the drug which is found in breast milk and its potential effects on a neonate or infant.

Both methotrexate and leflunomide are contraindicated in mothers with PsA while breast feeding.

The only TNFi for which a human study has investigated the excretion of the drug into breast milk is certolizumab pegol. This drug has been found to be minimally excreted in breast milk. The CRADLE study looked at the level of drug in the breast milk of 17 lactating mothers after three or more doses of certolizumab pegol. Multiple samples were taken over a single dosing period. In 56% of the samples no drug was detected. In the remaining samples, very low levels of drug were detected (less than 1% of the expected mean drug plasma level in the mother). The authors concluded that treatment with certolizumab pegol is compatible with nursing.

Nonsteroidal anti-inflammatory drugs may be taken during lactation. If corticosteroids are needed, they should be given at the lowest possible dose.

Medications Used to Treat PsA and their Potential Effects on Pregnancy and Lactation

Table 2 summarizes key information for the medications discussed below.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Type of drug</th>
<th>Passes through the placenta</th>
<th>Teratogenic</th>
<th>Long-term effects in children</th>
<th>Effects on fertility</th>
<th>Adverse effects on fetus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methotrexate (MTX) (Rasuvo, Otrexup, Rheumatrex, or generic)</td>
<td>csDMARD</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>• Impaired fertility • Menstrual dysfunction</td>
<td>• Cytopenia • Fetal death • Congenital anomalies</td>
</tr>
<tr>
<td>Leflunomide (Arava)</td>
<td>csDMARD</td>
<td>Unknown</td>
<td>Inconclusive data</td>
<td>None published</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sulfasalazine (Azulfidine)</td>
<td>csDMARD</td>
<td>+</td>
<td>-</td>
<td>Unknown</td>
<td>In men: • Oligospermia • Decreased sperm motility • Abnormal sperm</td>
<td>Reports of aplastic anemia at &gt;2 g maternal dose</td>
</tr>
<tr>
<td>Hydroxychloroquine (Plaquenil)</td>
<td>csDMARD</td>
<td>Unknown</td>
<td>+</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>TNFi</td>
<td>+</td>
<td></td>
<td>Not reported</td>
<td>Not reported</td>
<td>Unknown</td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>TNFi</td>
<td>Low</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>TNFi</td>
<td>+</td>
<td></td>
<td>Not reported</td>
<td>Not reported</td>
<td>Unknown</td>
</tr>
<tr>
<td>Certolizumab (Cimzia)</td>
<td>TNFi</td>
<td>Very low</td>
<td>Unknown</td>
<td>None to date</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>TNFi</td>
<td>+</td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Golimumab (Simponi)</td>
<td>TNFi</td>
<td>+</td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Ustekinumab (Stelara)</td>
<td>IL-12/23i</td>
<td>+</td>
<td></td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Table 2. Drugs commonly used in the management of patients with PsA—Key information relevant for women
<table>
<thead>
<tr>
<th>Medication</th>
<th>Type of drug</th>
<th>Passes through the placenta</th>
<th>Teratogenic</th>
<th>Long-term effects in children</th>
<th>Effects on fertility</th>
<th>Adverse effects on fetus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apremilast (Otezla)</td>
<td>PDE4i</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Secukinumab (Cosentyx)</td>
<td>IL-17A antagonist</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Ixekizumab (Taltz)</td>
<td>IL-17A antagonist</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Tofacitinib (Xeljanz)</td>
<td>JAKi</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>Abatacept (Orencia)</td>
<td>T cell costimulation inhibitor</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>NSAIDs</td>
<td></td>
<td>+</td>
<td>-</td>
<td>Unknown</td>
<td>Cases of inhibition of follicle rupture</td>
<td>Decreased renal blood flow; Late narrowing of the ductus arteriosus</td>
</tr>
<tr>
<td>Prednisone</td>
<td>Corticosteroid</td>
<td>Limited</td>
<td>Increase in oral clefts</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Rare cataracts; Adrenal insufficiency; Infection</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>Glucocorticoid</td>
<td>+</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Neuro-developmental abnormalities</td>
</tr>
</tbody>
</table>

+ = yes or positive; - = no or negative

csDMARD, conventional synthetic disease-modifying antirheumatic drug; IgG, immunoglobulin G; IL-12/23i, interleukin-12/23 inhibitor; IL-17A, interleukin-17A; JAKi, Janus Kinase inhibitor; MTX, methotrexate; MTXPGs, methotrexate polyglutamates; PDE4i, phosphodiesterase 4 inhibitor; TNFi, tumor necrosis factor inhibitor
According to the ACR, and EULAR methotrexate should not be used during pregnancy or lactation. Methotrexate has been associated with fetal death and serious congenital anomalies. In both men and women, it can decrease fertility. Its use is contraindicated during the 3-6 months prior to trying to conceive and throughout pregnancy and lactation.\(^{29, 46, 47}\)

Leflunomide is also contraindicated in pregnancy and lactation as well as during the 3 to 6 month period prior to conception. It can remain in a patient’s system for up to 2 years after it is stopped. Before trying to conceive women who have taken this drug in the past should be tested to determine if the drug is still in their system. Women who are currently taking leflunomide or have taken it in the past and test positive for it and want to become pregnant or find that they are pregnant must undergo a drug elimination procedure described in the [FDA information for this drug].\(^{65}\) Additional leflunomide (Arava) information for mothers is available in the [Mother to Baby Fact Sheet].\(^{46}\)

Hydroxychloroquine (Plaquenil) and sulfasalazine (Azulfidine) are csDMARD considered to be safe during pregnancy and lactation according to the ACR and EULAR.\(^{46, 47}\)

Corticosteroids may be used at the lowest possible dose throughout pregnancy if needed.\(^{46, 47}\) As discussed above NSAIDs should be used with caution during conception and early pregnancy. They should not be used in the third trimester.

Certolizumab pegol (Cimzia), a TNFi drug, is the only drug for which there is a small amount data available from clinical studies during pregnancy and lactation.\(^{54, 64}\) In the CRIB study,\(^{54}\) 16 pregnant women, all of whom had a rheumatic disorder and were 30 or more weeks pregnant, were followed. Two neonates were not included in the final analysis, because they did not meet the study protocol. In 13 neonates at birth, no drug was detected and in the remaining neonate the level of the drug was .09% of the level detected in the mother. All of the mothers had the expected blood levels of the drug at delivery. Three infants had a very low level of certolizumab pegol detected in cord blood. The drug was not detectable in any of the infants at 4 and 8 weeks after delivery. With no to minimal transfer of certolizumab pegol to the infants detected, the study concluded that treatment with certolizumab pegol was compatible with pregnancy.\(^{54}\)

The other study, (the CRADLE study), followed 17 nursing mothers who had received 3 or more doses of certolizumab pegol while nursing. Multiple samples of breast milk were taken over a single dosing period. In 56% of the samples no drug was detected. In the remaining samples, very low levels of drug were detected. The authors concluded that treatment with certolizumab pegol was acceptable for nursing mothers.\(^{64}\)

According to the EULAR recommendation, certolizumab pegol should be considered in both pregnant and nursing mothers, if needed to control the mother’s disease.\(^{46}\) However, larger studies are required to confirm these observations.

Adalimumab (Humira) is transferred across the placenta, and small amounts can found in human milk as well.\(^{34}\) However, according to the National Institutes of Health [LactMed] database, this drug is most likely destroyed in the infant’s GI tract, but caution is advised. In their recommendation, EULAR considers this drug to be compatible with nursing.\(^{46}\)
It is not known whether infliximab (Remicade) can affect fertility. It crosses the placenta and can be detected in the blood of infants for up to 6 months after birth when mothers took it during pregnancy. Children exposed to infliximab may have an increased risk for infection and should not receive a live virus vaccination until 6 months after birth. It is not known if this drug is excreted in human milk. The Remicade package insert recommends against breast feeding while taking infliximab. Whether or not the drug should be discontinued when nursing should be decided by the patient in consultation with her physician(s).46, 54

Small amounts of etanercept (Enbrel) have been found to cross the placenta and were found in cord blood at delivery. According to the Enbrel package insert, etanercept should only be used during pregnancy if there is no other safer drug available. Information regarding whether or not this drug is found in human milk is inconsistent. According to EULAR’s systematic review there is low excretion of this drug into breast milk; therefore, EULAR considers etanercept to be compatible with nursing.46 However, if a mother has taken etanercept during pregnancy and is considering nursing, she should discuss with her physicians whether the drug should be stopped or changed to a different, safer medication or if she should stop nursing.36, 46

Golimumab (Simponi, Simponi Aria) is a monoclonal antibody that is transported across the placenta during the third trimester of pregnancy.35 It is recommended that woman take this drug during pregnancy only if there is no other option. Infants born to women who have taken this drug while pregnant have an increased risk of infection and should not be given live virus vaccines until 6 months after birth. It is unknown if this drug is excreted in human milk. If a mother on golimumab plans to breast feed her infant she should discuss with her physician(s) whether or not to continue this drug or to discontinue breast feeding.35

Abatacept (Orencia) is a T cell costimulatory inhibitor. It is a large molecule and therefore only small amounts of this drug would be expected to be excreted in human milk. According to EULAR, there is limited information on abatacept in pregnancy. Therefore, it is recommended that abatacept be replaced before and during pregnancy, unless there is no other safer medication that can control the mother’s PsA.46 According to the LactMed database, if this drug is essential for the control of the mother’s disease, then it can be used while nursing, unless the mother and her physician(s) prefer a different drug. At this time, there are no studies that address the safety of abatacept in a nursing mother.73

Ustekinumab (Stelara®) is an IL-12/23 antagonist. According to the FDA, there is insufficient information about the use of Stelara in pregnancy to comment on its safety. In addition, EULAR cautions about the use of this drug during pregnancy because current data is very limited. Ustekinumab should only be used when there is no other drug available that is considered to be safer for the mother and her unborn child. There is also no data on whether or not this drug is found in human milk.67 Therefore, EULAR discourages its use during lactation but indicates that it can be used if there is no alternative for the mother.46

Apremilast (Otezla®) is a PDE4 antagonist. There is insufficient information about the use of this drug in pregnant women or risks to the fetus. The FDA suggests that this drug be used in pregnancy or lactating women only if there is no other alternative.69
Secukinumab (Cosentyx®) is an IL-17A antagonist. According to the FDA, there is inadequate information regarding the use of this drug during pregnancy; therefore, it should only be used if the benefits outweigh the risks. In nursing mothers, secukinumab should be used with caution.\textsuperscript{70}

Ixekizumab (Taltz®) is also an IL-17A antagonist. According to the FDA, there is no data available about the use of this drug in pregnancy to determine its risks. This drug may cross the placenta. It is not known if it is excreted in human milk. It should be used with caution in lactating women.\textsuperscript{71}

Tofacitinib (Xeljanz®) is a JAK inhibitor for which there is insufficient data to determine the risk of adverse fetal outcomes. There is also no data on the presence or absence of tofacitinib in human milk. According to the Xeljanz package insert and EULAR, nursing while taking tofacitinib is not recommended.\textsuperscript{46} If it must be used while breast feeding, it should be taken at least 18 hours before nursing. If the mother is using Xeljanz XR, then it should be taken at least 36 hours before nursing.\textsuperscript{72}

There are Pregnancy Registries designed to gather information on maternal-fetal outcomes in patients taking Enbrel, Orencia, Stelara, Otezla, Xeljanz, and Cimzia. Information about how to provide information to these registries is listed in the package inserts for each drug. Healthcare providers are encouraged to register their patients. The telephone number for the registry may be obtained from the package inserts at the URLs provided in the \textit{References}.

United Rheumatology strongly suggests that rheumatologists work closely with obstetricians and/or maternal fetal specialists, dermatologists, and primary care providers when they are treating women with PsA of child bearing age who are pregnant or who are planning to become pregnant.
### Glossary

| **Inflammatory back pain (IBP)** | Chronic back pain for at least 3 months and four of the following five parameters:<sup>28</sup>  
1. Age of onset <40 years  
2. Insidious onset  
3. Improvement with exercise  
4. Lack of improvement with rest  
5. Nocturnal pain that improves upon arising |
| **Minimal disease activity (MDA)** | Very low disease activity is a measure of PsA activity when the patient meets five of the following:  
1. Tender joints ≤1  
2. Swollen joints ≤1  
3. Pain VAS ≤15  
4. Patient Global Assessment ≤20  
5. MDHAQ <.5  
6. PASI <1 or BSA ≤3  
7. Tender enthesal points ≤1 |
| **Multidimensional Health Assessment Questionnaire (MDHAQ)** | The MDHAQ is a practical patient self-report tool that patients can complete in the waiting room. A form is available at [https://integrationacademy.ahrq.gov/sites/default/files/MDHAQ_0.pdf](https://integrationacademy.ahrq.gov/sites/default/files/MDHAQ_0.pdf). |
| **Oral small molecule (OSM) drugs** | This group of drugs consists of methotrexate, sulfasalazine, cyclosporin, leflunomide, and apremilast |
| **Psoriasis Area and Severity Index (PASI)** | Severity of psoriasis of the skin, based on the body surface area involved. The affected body surface area is the percent of skin on the head, trunk, arms, and legs with erythema, induration, and scaling of the skin; with 1% body surface area equivalent to the surface area of the patient’s palm (including the fingers). A free PASI online calculator can be found at [http://pasi.corti.li/](http://pasi.corti.li/). |
Very low disease activity (VDLA) is a measure of PsA activity when the patient meets all of the following:

1. Tender joints ≤ 1
2. Swollen joints ≤ 1
3. Pain VAS ≤ 15
4. Patient Global Assessment ≤ 20
5. MDHAQ < .5
6. PASI < 1 or BSA ≤ 3
7. Tender enthesal points ≤ 1
References


52. Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). What are some factors that make a pregnancy high risk?


### Document Updates

<table>
<thead>
<tr>
<th>Document Version</th>
<th>Description of Changes</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>1.1.2016</td>
<td>Creation of first version</td>
<td>Aug 2016</td>
</tr>
<tr>
<td>1.1.2017</td>
<td>2017 update</td>
<td>Oct 2017</td>
</tr>
<tr>
<td>1.1.2019</td>
<td>2018/19 update</td>
<td>Apr 2019</td>
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