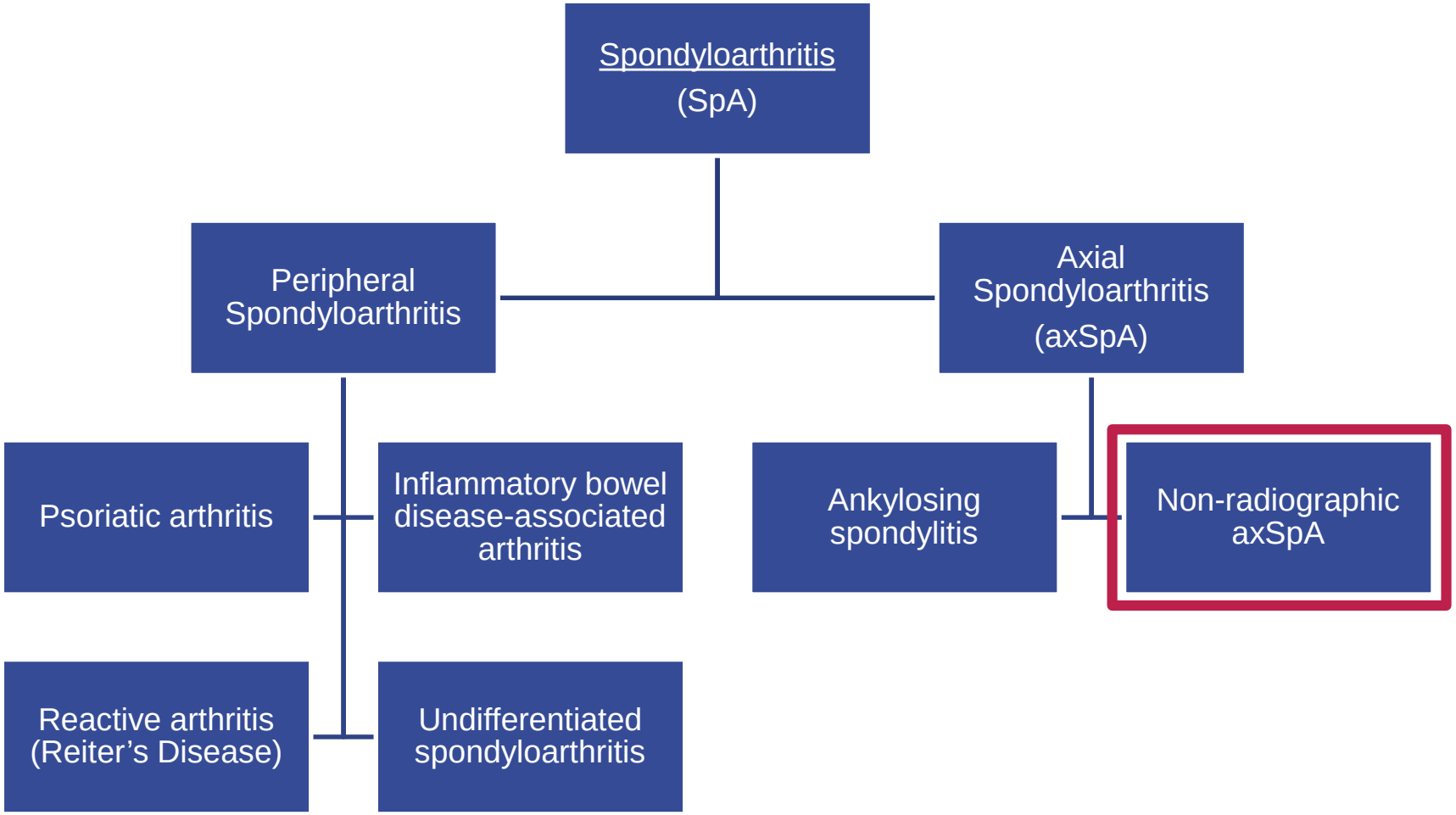
Non-Radiographic Axial Spondyloarthritis ICD-10 Code Proposal

ICD-10 Coordination and Maintenance Committee Meeting

September 8-9, 2020

Jeffrey Stark, MD, FACR
Head of Medical Immunology, UCB

nr-AxSpA Is a Member of the Spondyloarthritis Family of Diseases



1. Raychaudhuri SP, Deodhar A. *J Autoimmun.* 2014;48-49:128-133.

ASAS Classification Criteria Provide a Formal Definition of nr-AxSpA

SpA features

- IBP
- Arthritis
- Enthesitis (heel)
- Uveitis
- Dactylitis
- Psoriasis
- CD/UC
- Good response to NSAIDs
- Family history of SpA
- HLA-B27
- Elevated CRP

In patients with back pain for ≥3 months and age of onset <45 years

Imaging criteria: sacroiliitis on imaging + ≥1 SpA feature

Active inflammation on MRI highly suggestive of sacroiliitis associated with SpA

OR

Definite radiographic sacroiliitis (grade 2 bilaterally or grade 3-4 unilaterally)

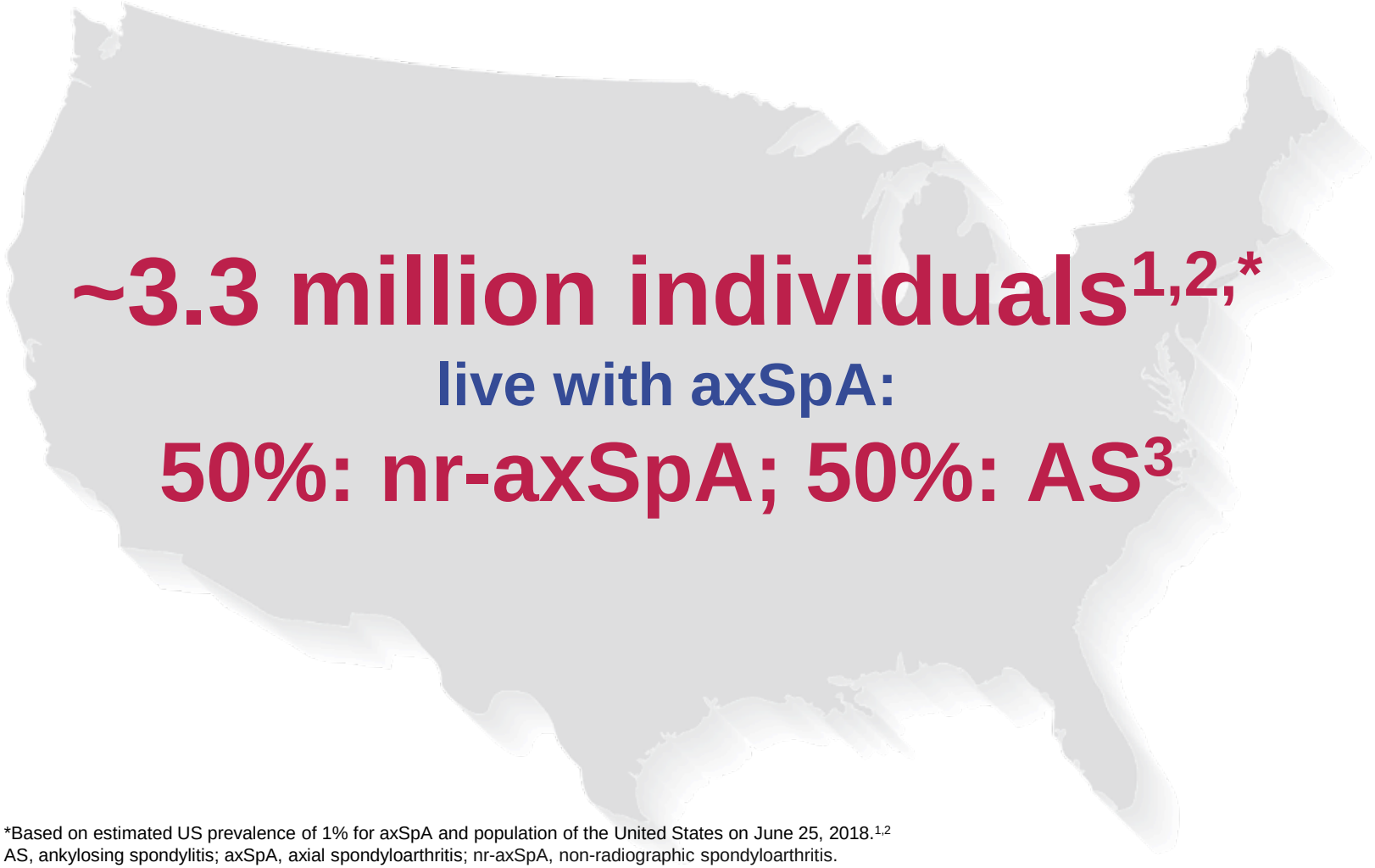
OR

Clinical criteria: HLA-B27 + ≥2 other SpA features

ASAS, Assessment of SpondyloArthritis international Society; axSpA, axial spondyloarthritis; CD, Crohn's disease; CRP, C-reactive protein; HLA-B27, human leukocyte antigen-B27; IBP, inflammatory back pain; MRI, magnetic resonance imaging; nr-axSpA, non-radiographic axial spondyloarthritis; NSAID, nonsteroidal anti-inflammatory drug; SpA, spondyloarthritis; UC, ulcerative colitis.

Rudwaleit M, et al. *Ann Rheum Dis*. 2009;68(6):777-783.

Prevalence of nr-AxSpA



~3.3 million individuals[1,2,*]

live with axSpA:

50%: nr-axSpA; 50%: AS[3]

Approximately
1.7 million
individuals in the U.S. today have non-radiographic axSpA

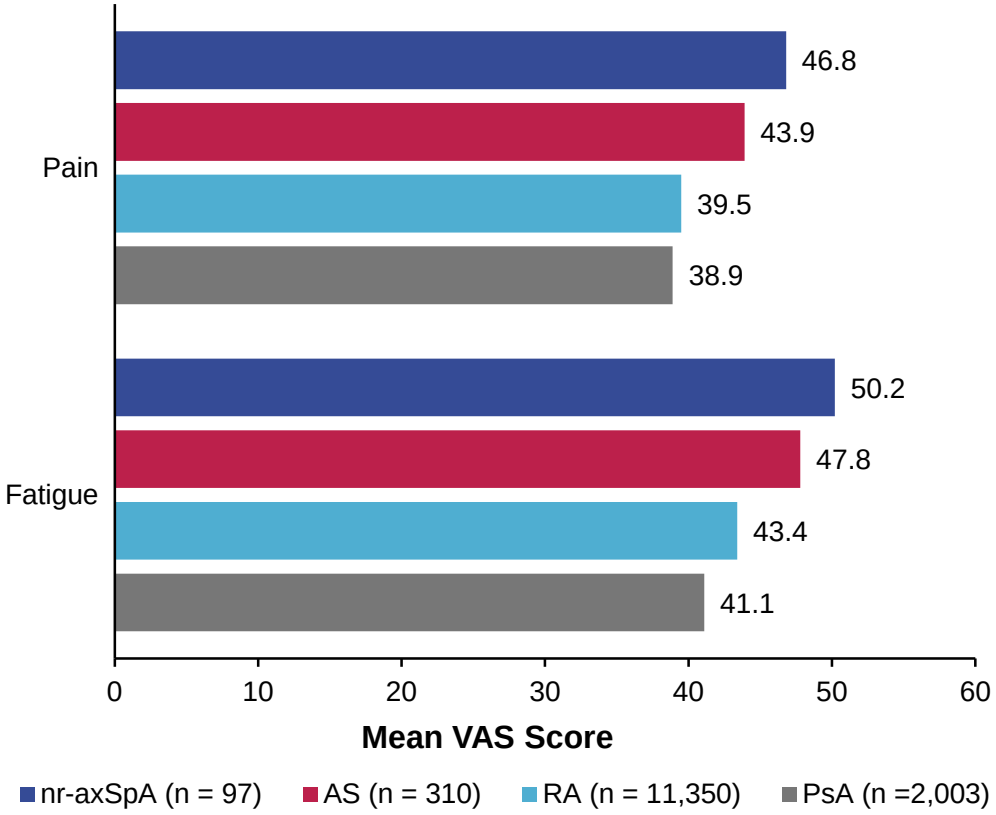
*Based on estimated US prevalence of 1% for axSpA and population of the United States on June 25, 2018.[1,2]
AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; nr-axSpA, non-radiographic spondyloarthritis.

© iStock.com/Eivaisla

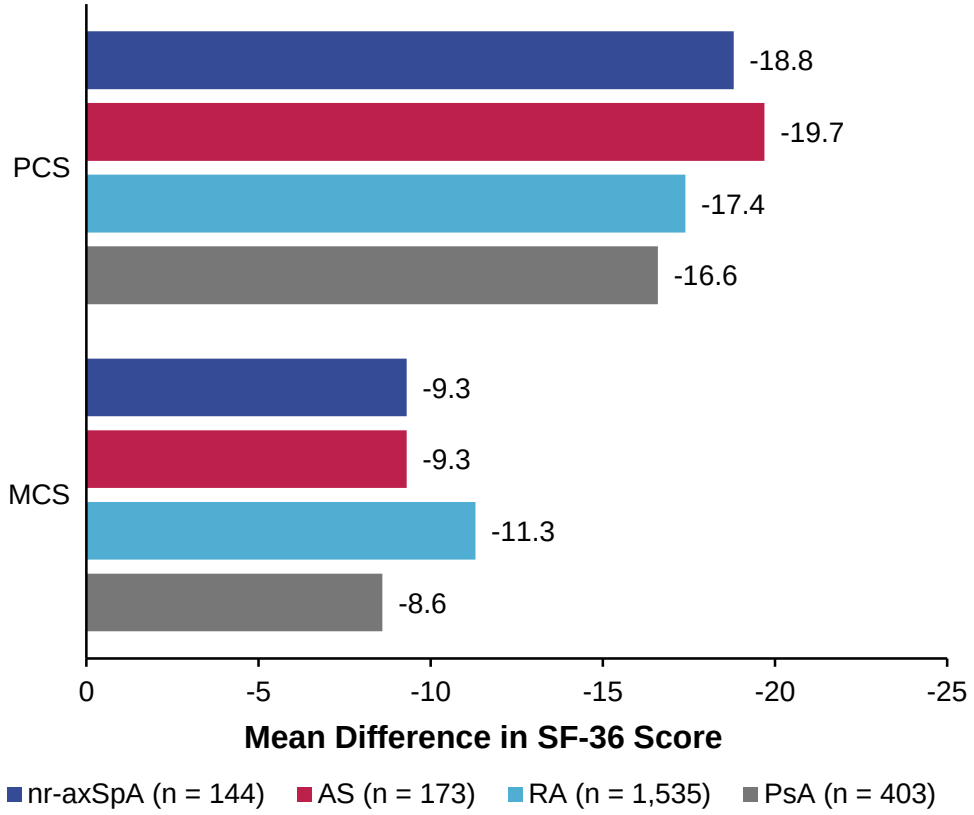
1. Reveille JD, et al. *Arthritis Care Res*. 2012;64(6):905-910. 2. United States Census Bureau. U.S. and World Population Clock. https://www.census.gov/popclock/. Accessed March 3, 2020.
3. Baraliakos X, Braun J. *RMD Open*. 2015;1(Suppl 1):e000053. doi: 10.1136/rmdopen-2015-000053.

The Burden of nr-AxSpA is Similar to that of Other Common Rheumatic Diseases

Patient-Reported Outcomes[1,2,*]



SF-36 Physical and Mental Components[3,†]

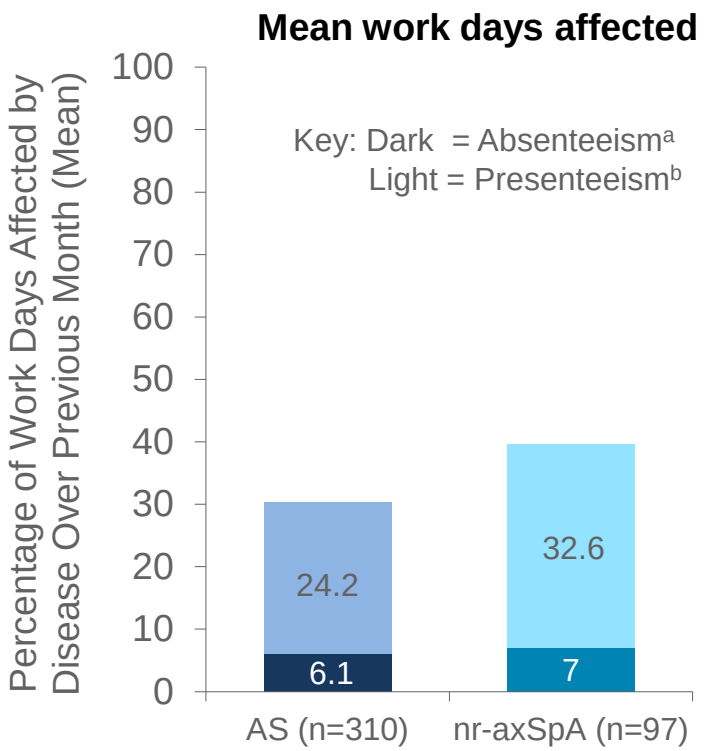


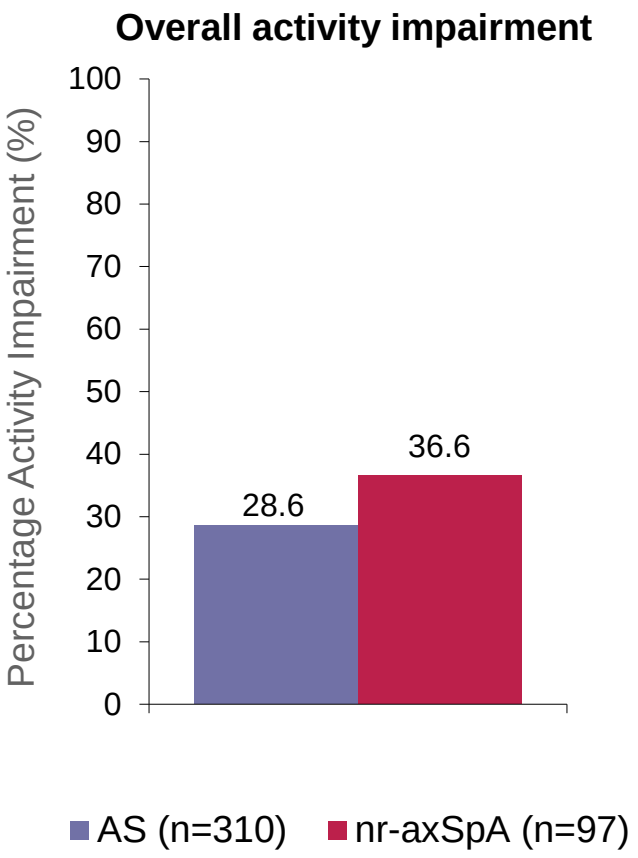
*High scores indicate worse disease activity. These data are from the Corrona RA registry and the Corrona PsA/SpA registry, which are prospective, multicenter, observational disease-based registries in the US that use a 0-100 VAS. As in any observational real-world study, no longitudinal analyses were performed to compare patients over time and the AS and nr-axSpA patient population may not be representative of all adults with axSpA.
†HRQoL scores were age- and sex-matched using SF-36 component scores. SF-36 is a set of generic, coherent, and easily administered quality-of-life measures.
AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; HRQoL, health-related quality of life; MCS, Mental Component Summary; nr-axSpA, non-radiographic axial spondyloarthritis; PCS, Physical Component Summary; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SF-36, 36-Item Short Form Health Survey; SpA, spondyloarthritis; VAS, visual analog scale.

1. Mease PJ, et al. *Arthritis Care Res (Hoboken)*. 2018;70(11):1661-1670. 2. Mease PJ, et al. *Arthritis Rheumatol*. 2018;70(suppl 10). 3. Mease PJ, et al. *Ann Rheum Dis.* 2013;72(suppl 3):A766-A767.

Disability and Impairment in nr-axSpA

Burden of nr-axSpA and AS on Workplace Productivity at Study Baseline





AS: Ankylosing spondylitis; **nr-axSpA**: Non-radiographic axial spondyloarthritis.
[a]Absenteeism = work days missed due to arthritis over previous month; [b]Presenteeism = days with work productivity reduced by ≥50% due to arthritis over previous month (does not include days counted in absenteeism).

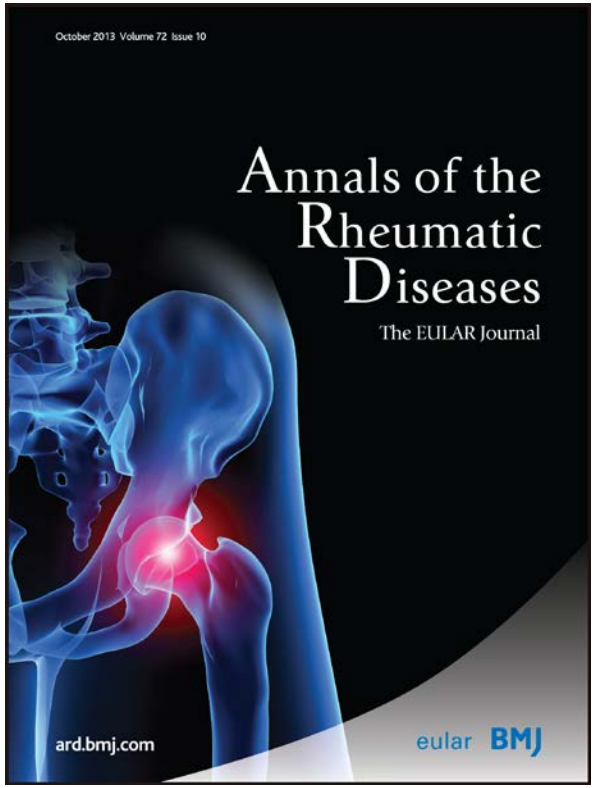
Mease et al, 2018, Characterization of Patients With Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis in the US-Based Corrona Registry (in press).

nr-AxSpA Continues to Be a Focus of Active, Ongoing Research

A literature search on September 1, 2020 reveals 154 unique manuscripts published since July 2010 whose titles contain the precise term "non(-)radiographic axial spondyloarthritis".

THE LANCET

The Journal of Rheumatology



Source: https://pubmed.ncbi.nlm.nih.gov/. Accessed Sept 1, 2020.

Completed and Ongoing Clinical Trial Programs in nr-AxSpA

FDA-Approved Treatments for nr-AxSpA		
certolizumab pegol CIMZIA ®	UCB	Approved March 2019
ixekizumab Taltz ®	Lilly	Approved June 2020
secukinumab Cosentyx ®	Novartis	Approved June 2020

Ongoing Clinical Trials[1]	
Phase Two	filgotinib
Phase Three	bimekizumab, secukinumab IV, secukinumab SC, tildrakizumab
Phase Four	golimumab

1. Source: www.clinicaltrials.gov. Accessed Sept 1, 2020.

Professional and Patient Societies Have Developed Formal Treatment Guidelines for nr-AxSpA

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SPECIAL ARTICLE

2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis

Michael M. Ward,[1] Atul Deodhar,[2] Lianne S. Gensler,[3] Maureen Dubreuil,[4] David Yu,[5] Muhammad Asim Khan,[6] Nigil Haroon,[7] David Borenstein,[8] Runsheng Wang,[9] Ann Biehl,[1] Meika A. Fang,[10] Grant Louie,[11] Vikas Majithia,[12] Bernard Ng,[13] Rosemary Bigham,[14] Michael Pianin,[15] Amit Aakash Shah,[14] Nancy Sullivan,[17] Marat Turgunbaev,[14] Jeff Oristaglio,[17] Amy Turner,[16] Walter P. Maksymowych,[18] and Liron Caplan[19]

Guidelines and recommendations developed and/or endorsed by the American College of Rheumatology (ACR) are intended to provide guidance for particular patterns of practice and not to dictate the care of a particular patient. The ACR considers adherence to the recommendations within this guideline to be voluntary, with the ultimate determination regarding their application to be made by the health care provider in light of each patient's individual circumstances. Guidelines and recommendations are intended to promote beneficial or desirable outcomes but cannot guarantee any specific outcome. Guidelines and recommendations developed and endorsed by the ACR are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice. ACR recommendations are not intended to dictate payment or insurance decisions. These recommendations cannot adequately convey all uncertainties and nuances of patient care.

The American College of Rheumatology is an independent, professional, medical and scientific society that does not guarantee, warrant, or endorse any commercial product or service.

Objective. To update evidence-based recommendations for the treatment of patients with ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (SpA).

Methods. We conducted updated systematic literature reviews for 20 clinical questions on pharmacologic treatment addressed in the 2015 guidelines, and for 26 new questions on pharmacologic treatment, treat-to-target strategy, and use of imaging. New questions addressed the use of secukinumab, ixekizumab, tofacitinib, tumor necrosis factor inhibitor (TNFi) biosimilars, and biologic tapering/discontinuation, among others. We used the Grading of Recommendations, Assessment, Development and Evaluation methodology to assess the quality of evidence and formulate recommendations and required at least 70% agreement among the voting panel.

Results. Recommendations for AS and nonradiographic axial SpA are similar. TNFi are recommended over secukinumab or ixekizumab as the first biologic to be used. Secukinumab or ixekizumab is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi. TNFi, secukinumab, and ixekizumab are favored over tofacitinib. Co-administration of low-dose methotrexate with TNFi is not recommended, nor is a strict treat-to-target strategy or discontinuation or tapering of biologics in patients with stable disease. Sulfasalazine is recommended only for persistent peripheral arthritis when TNFi are contraindicated. For patients with unclear disease activity, spine or pelvis magnetic resonance imaging could aid assessment. Routine monitoring of radiographic changes with serial spine radiographs is not recommended.

Conclusion. These recommendations provide updated guidance regarding use of new medications and imaging of the axial skeleton in the management of AS and nonradiographic axial SpA.

1599

Ward MM, et al. *Arthritis Care Res (Hoboken).* 2019. doi: 10.1002/acr.24025. [Epub ahead of print].

Recently Approved Indexed Codes for nr-AxSpA[1]

Subcategory	M46.80	Non-radiographic axial spondyloarthritis (nr-axSpA)
Code	M46.81	nr-axSpA of occipito-atlanto-axial region
Code	M46.82	nr-axSpA of cervical region
Code	M46.83	nr-axSpA of cervicothoracic region
Code	M46.84	nr-axSpA of thoracic region
Code	M46.84	nr-axSpA of lumbar region
Code	M46.85	nr-axSpA of thoracolumbar region
Code	M46.86	
Code	M46.87	nr-axSpA of lumbosacral region
Code	M46.88	nr-axSpA of sacral and sacrococcygeal region
Code	M46.89	nr-axSpA of multiple sites

Positive aspects:

- Implementation on October 1, 2020
- Raise awareness and promote recognition
- Encourage consistent coding practice

Areas for improvement:

- Potential miscategorization of lumbar disease (M46.84 vs. M46.86) ?
- Not specific for nr-axSpA

1. Source: https://www.cms.gov/medicare/icd-10/2021-icd-10-cm. Accessed Sept 1, 2020

Summary of Rationale for New nr-AxSpA ICD-10 Subcategory

- Improve **non-radiographic axSpA** patient identification for real world evidence data generation to provide a deeper understanding of the condition
- Increase awareness of **non-radiographic axSpA** in the clinical community, improving the time to and the accuracy of diagnosis, facilitating access to essential care
- Ensure **non-radiographic axSpA** receives representation in the coding manual similar to other diseases of equal prevalence and severity (e.g., rheumatoid arthritis, ankylosing spondylitis)
- Creation of a new category is supported by American College of Rheumatology (ACR), Spondylitis Association of America (SAA), Coalition of State Rheumatology Organizations (CSRO), and others