Reference Guide
AS and nr-axSpA Disease Criteria and Activity Measures

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Inspired by **patients.**
Driven by **science.**

AxSpA Clinical Resource Toolkit Version 1, November 2019

AS and nr-AxSpA Disease Activity Measures

Ankylosing Spondylitis Disease Activity Score (ASDAS)[1-3]

ASDAS is a validated, highly discriminatory instrument for assessing a patient's disease activity, comprising:

Patient-reported outcomes
1. Back pain
2. Duration of morning stiffness
3. Patient's Global Assessment of Disease Activity
4. Peripheral pain/swelling

Objective evidence of systemic inflammation
5. C-reactive protein (CRP)

$$ASDAS_{CRP} = 0.1216 \times \text{total back pain} + 0.1106 \times \text{patient global} + 0.0736 \times \text{peripheral pain/swelling} + 0.0586 \times \text{duration of morning stiffness} + 0.5796 \times \ln(CRP+1)$$

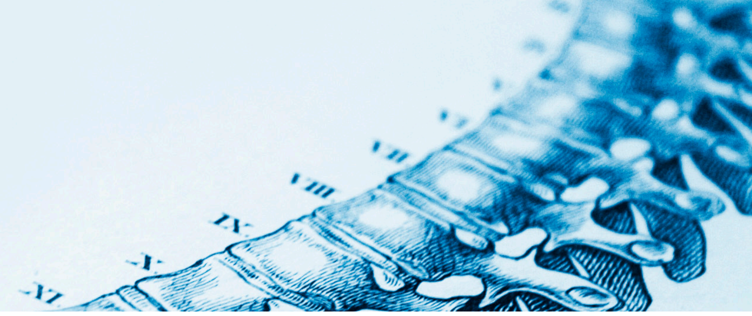
ASDAS-ID	ASDAS-LDA	ASDAS-HDA	ASDAS-vHDA
<1.3: inactive disease[2]	≥1.3 to <2.1: low activity[2]	≥2.1 to ≤3.5: high activity[2]	>3.5: very high activity[2]

Lowest possible ASDAS value: 0.6
Clinically important improvement (CII): decrease ≥ 1.1 units vs baseline[2]
Major improvement (MI): decrease ≥ 2.0 units vs baseline – a more stringent outcome than ASAS40[2]

1. Sieper J, et al. *Ann Rheum Dis.* 2009;68(suppl 2):ii1-ii44.
2. Machado P, et al. *Ann Rheum Dis.* 2011;70(1):47-53.
3. van der Heijde D, et al. *Ann Rheum Dis.* 2009; 68(12): 1811-1818.

ASDAS Calculator

https://www.asas-group.org/clinical-instruments/asdas-calculator/



AS and nr-AxSpA Disease Activity Measures

ASAS Response Criteria[1]

ASAS20	• **Improvement of ≥20% and ≥1 unit** in at least 3 of the 4 domains on a scale of 0 to 10 • No worsening of ≥20% and ≥1 unit in remaining domain
ASAS40	• **Improvement of ≥40% and ≥2 units** in at least 3 of the 4 domains on a scale of 0 to 10 • No worsening at all in remaining domain
ASAS partial remission	• **A value of <2 units** in each of the 4 domains on a scale of 0 to 10
ASAS5/6	• **Improvement of ≥20%** in at least 5 of the 6 domains on a scale of 0 to 10

1. Ranganath V, et al. Clin Exp Rheumatol. 2006;24(suppl 43):S14-S21.

ASAS Domains

1. Patient global assessment: VAS
2. Pain: VAS, nocturnal
3. Function: BASFI
4. Inflammation: Mean of BASDAI questions 5 and 6
5. CRP*: Blood sample tests
6. Spinal mobility: BASMI

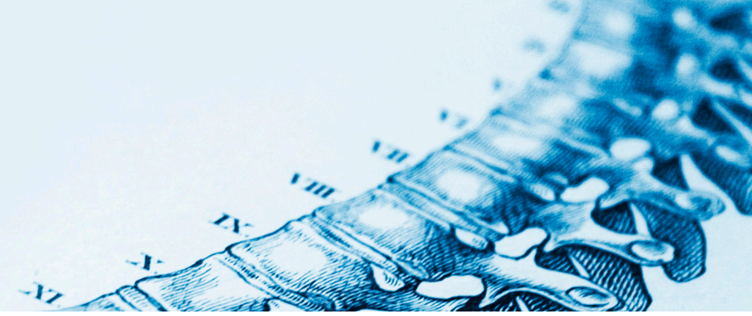
a. CRP and spinal mobility are included only in the ASAS5/6 response criteria

BASMI: Bath Ankylosing Spondylitis Metrology Index

- The BASMI comprises a combination of five clinical measurements that reflect axial mobility:[1]
  - Tragus to wall distance
  - Lumbar flexion
  - Cervical rotation
  - Lumbar side flexion
  - Intermalleolar distance
- Each movement is graded according to linear function, and the mean of the scores gives a total BASMI score between 0 and 10.[1]

1. Sieper J et al. *Ann Rheum Dis.* 2009;68(suppl II):ii1–ii44. 2. UCB Data on File (AS001 Protocol Amendment 6. 2013. p60)

For more information, modelling and videos of BASMI components, visit: http://www.carearthritis.com/



Bath Ankylosing Spondylitis Functional Index (BASFI)

- **The BASFI is a patient self-administered questionnaire used to determine physical functional ability in patients.[1]**
- **The mean of these scores is the final BASFI score (range 0–10).[1]**

*For a BASFI calculator consider visiting http://basdai.com/BASFI.php

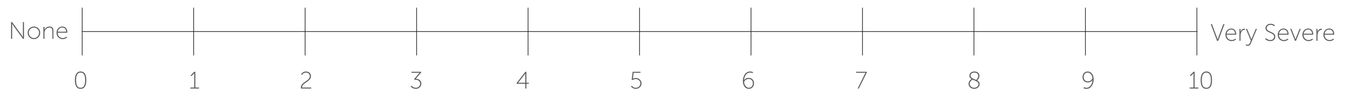
Practice/Institution:_______________________ **Physician/Investigator's Name:** _________________________

Bath Ankylosing Spondylitis Functional Index* (BASFI)

Patient Name__________________________________ **Date**_______________

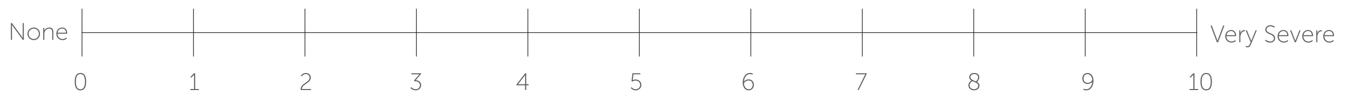
Please draw a mark on each line below to indicate your answer to each question relating to the past week.

1. How would you describe your overall level of **fatigue or tiredness?**



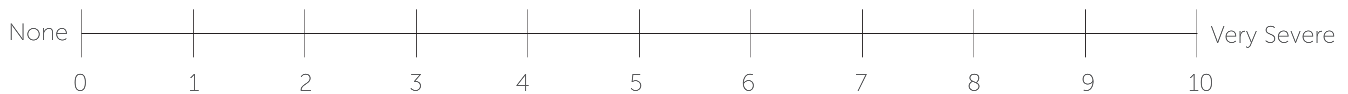
2. How would you describe your overall level of **neck, back or hip pain?**

3. How would you describe your overall pain and swelling in joints **other than** the neck, back, and hips?



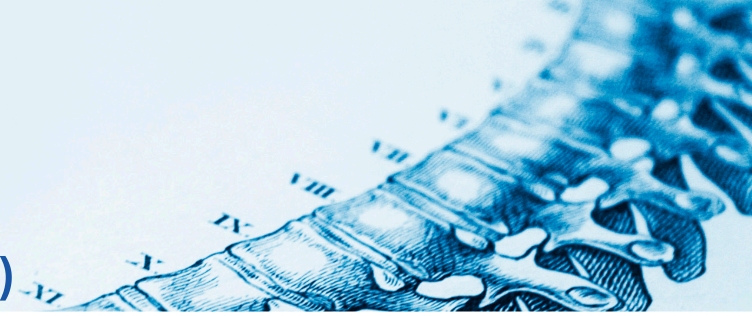
4. How would you describe your overall level of **discomfort** you have had from any areas tender to **touch or pressure?**

5. How would you describe the overall level of **morning stiffness** you have had **from the time you wake up?**



6. How long does your **morning stiffness** last from the time you wake up?

Score:_________________



Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

The BASDAI is a fully patient-reported measure of axial disease activity, in the form of a questionnaire composed of 6 items using numerical rating scales from 0 to 10:[1]

Practice/Institution:__________________ Physician/Investigator's Name: ___________________

The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

Patient Name___________________________________ Date________________

Please draw a mark on each line below to indicate your ability with each of the following activities during the past week:

1. Putting on your socks or tights without help or aids (e.g. sock aids)?

2. Bending forward from the waist to pick up a pen from the floor without an aid?

3. Reaching up to a high shelf without help or aids (e.g. helping hand)?

4. Getting up out of an armless dining room chair without using your hands or any other help

5. Getting up off the floor without any help from lying on your back?

6. Standing unsupported for 10 minutes without discomfort?

7. Climbing 12-15 steps without using a handrail or walking aid (one foot on each step)?

8. Looking over your shoulder without turning your body?

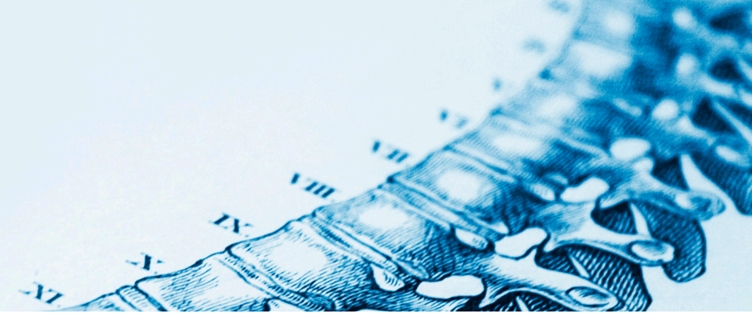
9. Doing physically demanding activities (e.g. physiotherapy exercises, gardening or sports)?

10. Doing a full day of activities whether it be at home or work?

BASDAI score $= \frac{Q1+Q2+Q3+Q4+((Q5+Q6)/2)}{5}$

***For a BASDAI calculator consider visiting http://basdai.com/BASDAI.php**

1. Sieper J et al. *Ann Rheum Dis.* 2009;68(suppl II):ii1–ii44.



AS and nr-AxSpA Disease Activity Measures

Total Pain and Nocturnal Pain (NRS)

- The total pain and nocturnal pain NRS measures the pain experienced by subjects via two questions:
  - One assesses the total spinal pain due to spondyloarthritis.
  - The other assesses the total spinal pain experienced at night.
- Pain and nocturnal pain NRS is a validated, patient-administered scale using numerical rating scales from 0 to 10.
- This assessment has been used previously to measure pain in axSpA patients.

Ankylosing Spondylitis Quality of Life (ASQoL)©

Disclaimer: Included for informational purposes, not intended for use in a single-patient setting

- The ASQoL is an instrument originally designed to assess AS-specific health-related quality of life.[1,2]
  - Additional validation has been performed to evaluate for axSpA patients.
- It is an 18-item, patient-reported questionnaire consisting of Yes/No response options and giving a final score between 0 and 18.[1]

1. Doward LC et al. *Ann Rheum Dis*. 2003;62(1):20–26. 2. UCB Data on File (AS001 Protocol Amendment 6. 2013. p61)

Modified Stoke Ankylosing Spondylitis Spinal Score* (mSASSS)

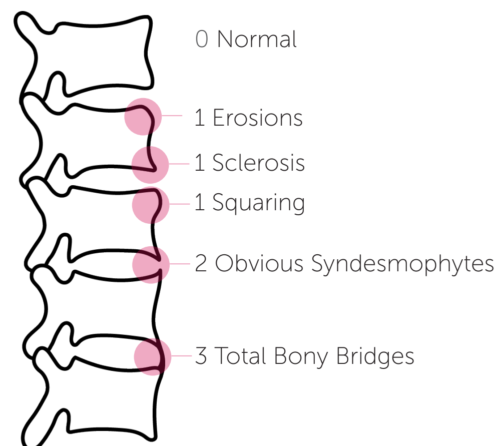
***Disclaimer: For informational purposes only. To be calculated by expert rheumatologists.**

- Lateral view lumbar and cervical spine
- Anterior sites of the vertebrae are scored for
  - Squaring
  - Erosions
  - Sclerosis
  - Syndesmophytes
- Score range 0-72

mSASSS recommended by ASAS

Creemers MCW, et al. *Ann Rheum Dis.* 2005;64(1):127-129.

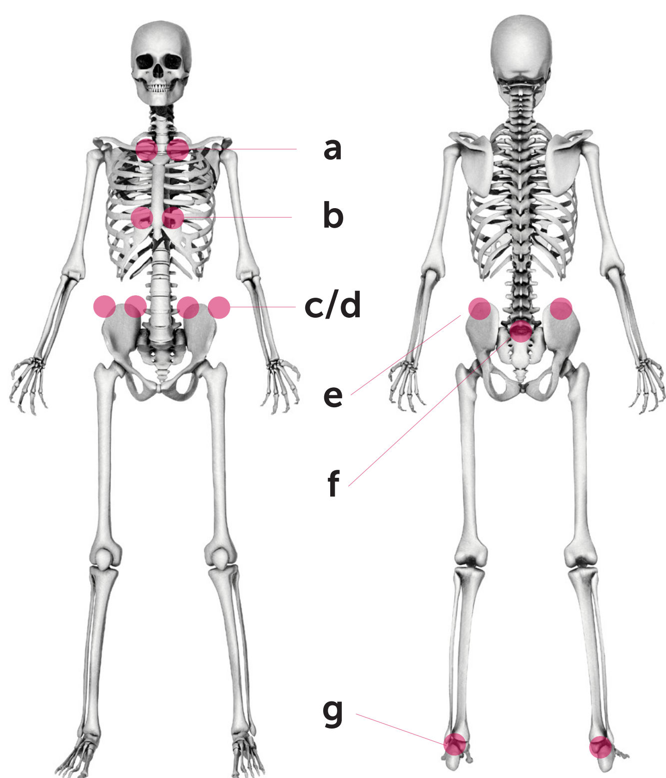
Point Scoring System



Maastricht Ankylosing Spondylitis Enthesitis Score (MASES)

- The MASES is an index of enthesitis, designed to be less time-consuming and more feasible to perform than alternative enthesitis scores, but with comparable properties.[1]
- Enthesitis is scored in the following areas by recording response to palpation as painful/not painful (1 or 0). Scores are summated to indicate overall enthesitis.[1]

Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) and expanded sites[2]



Descriptor	Right	Left
1st costochondral (a)	absent present	absent present
7th costochondral (b)	absent present	absent present
Posterior superior iliac spine (e)	absent present	absent present
Anterior superior iliac spine (c)	absent present	absent present
Iliac crest (d)	absent present	absent present
Proximal Achilles (g)	absent present	absent present
Midline		
5th lumbar spinous process (f)	absent present	

Total Score:___________________________

Physician's Signature:___________________________

Heuft-Dorenbosch et al. *Ann Rheum Dis.* 2003;62:127–132.
https://rheuma.charite.de/fileadmin/user_upload/microsites/ohne_AZ/m_cc13/rheuma/Templates/MASES_eng.pdf

Sacroiliac joints (SIJ) Spondyloarthritis Research Consortium of Canada (SPARCC) scoring

Total maximum score is 72:

Presence of "bone marrow edema" = 48
Presence of "intense edema" = 12
Presence of "deep edema" = 12

Scoring Methodology - Ten Steps

1. All scores are dichotomous – present or absent, 1 or 0.
2. Only 6 coronal slices are assessed. Slices 4-9 are usually selected as those representing the largest proportion of the synovial compartment of the SI joints. Images scored at a second time point are selected to correspond as closely as possible to the first time point – normally 4-9, 3-8 or 5-10.
3. Only abnormalities on the STIR sequence are scored. T1 SE images are included for anatomical reference.
4. Score all lesions within the iliac bone. Within the sacrum, score lesions medially as far as the lateral border of the sacral foramina.
5. Sacral inter-foraminal bone marrow signal is used as the reference for normal to determine a threshold for increased signal in periarticular bone.
6. Each SI joint is divided into four quadrants: 1 upper iliac, 2 lower iliac, 3 upper sacrum, 4 lower sacrum. The presence of increased signal in each quadrant is recorded. Maximum score for two SI joints in each coronal slice is 8. Maximum score for 6 coronal slices = 48.
7. A score for “intense” may be assigned to each SI joint on each slice. High signal from slow flowing venous blood within presacral veins acts as a reference for assigning an “intense” reading score to a bone lesion. A score of 1 is assigned if “intense” signal is seen in any quadrant of an SI joint on a single slice. Maximum score per slice is therefore 2, and for 6 slices = 12.
8. A score for “deep” may be assigned to each SI joint on each slice. A lesion is graded as “deep” if there is homogeneous and unequivocal increase in signal extending over a depth of at least 1 cm from the articular surface. A score of 1 is assigned if “deep” signal is seen in any quadrant of an SI joint on a single slice. Maximum score per slice is therefore 2, and for 6 slices = 12.
9. Pre- and post-treatment MR images are scored together with observer blinded to time sequence.
10. Non-Spondyloarthritis control images and reference Spondyloarthritis cases are available at this website to attain familiarity with the scoring method:

    https://www.carearthritis.com/docs/MRI_of_the_SIJ-SPARCC_Scoring_methodology.pdf