Radiographic (Ankylosing Spondylitis) *and* Non-radiographic Axial Spondyloarthritis (ASp) LSCMMG Recommended High Cost Drug (HCD) Pathway

High cost drugs should only be used when non-pharmacological therapy and standard pharmacological therapy has not worked well enough or is not tolerated

Treatment should be initiated at each line of treatment with the most cost effective/least expensive, clinically appropriate drug, taking into account administration costs, required dose and product price per dose. Patient access schemes, where available, may affect drug prices.

Where appropriate, a biosimilar product should be used in preference to the originator brand.

If primary inefficacy, select a drug with a different mechanism of action.

A patient will be allowed to receive up to three lines of treatment. A 'line' of treatment is completed when a drug is administered and a patient shows secondary nonresponse after an initial response period, using NICE criteria.

Use	TNF	IL-17	JAK
Radiographic and Non-radiographic Axial Spondyloarthritis	Adalimumab Etanercept Golimumab Certolizumab	Ixekizumab Secukinumab Bimekizumab	Upadacitinib
Only radiographic Axial Spondyloarthritis	Infliximab		Tofacitinib

Criteria for discontinuing a drug but remaining at <u>current</u> line of therapy:

- **Primary non-response** i.e. lack of improvement of clinical signs and symptoms after 16 weeks for bimekizumab, secukinumab, tofacitinib and upadacitinib, 16 to 20 weeks for ixekizumab or 12 weeks for all other drugs; or,
- Drug withdrawn because of **adverse event or intolerance**.

Secondary nonresponse: discontinue drug and move on to <u>next line</u> of therapy

Treatment with another HCD is recommended, up to 3 <u>lines</u> of therapy, for people whose disease has stopped responding after an initial response **(secondary non-response)**.

- The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment.
- Assess the response to secukinumab, upadacitinib, bimekizumab and tofacitinib after 16 weeks of treatment.
- Assess the response to ixekizumab after 16-20 weeks of treatment.
- Treatment should only be continued if there is clear evidence of response, defined as:
  - a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units **and**
  - a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

Failure of third line treatment constitutes the end of the commissioned high cost drugs pathway