Lancashire & South Cumbria Medicines Management Group

NHS

Psoriasis in adults: LSCMMG Biologic and High Cost Drug Commissioning Pathway

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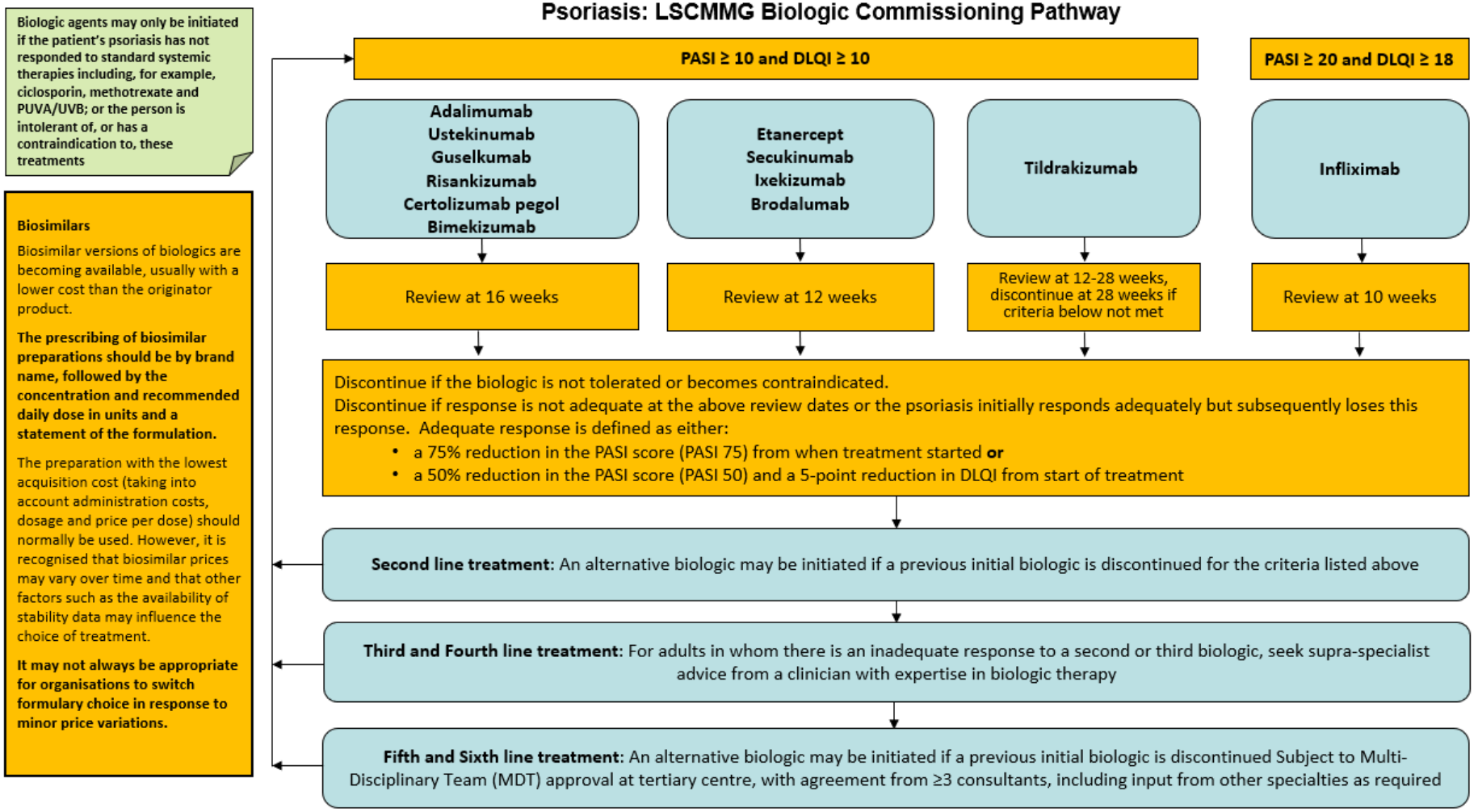
Version Number	Amendments made	Author	Date
1.0		David Prayle	12 April 2016
1.1		David Prayle	3 August 2016
1.2	Post LMMG minor accuracy changes made	David Prayle	14 September 2016
1.3	Addition of Ixekizumab	David Prayle	March 2018
1.4	Addition of brodalumab and nonbiologic high cost drugs, title updated to include reference to nonbiologic drugs	David Prayle	May 2018
1.5	Addition of guselkumab	David Prayle	November 2018
1.6	Addition of tildrakizumab and risaknizumab	Sharon Andrew, David Prayle	September 2019
1.7	Lines of biologic increased to six options. Position of Apremilast and dimethyl fumarate clarified.	David Prayle	July 2020
1.8	Addition of bimekizumab. Edits to improve flow of text.	Jill Gray	November 2022
Date of next review: November 2025			

Psoriasis: LSCMMG Biologic Commissioning Pathway



Background information

First-line therapy includes traditional topical therapies such as corticosteroids, vitamin D and vitamin D analogues, dithranol and tar preparations.

Second-line therapy includes phototherapy and systemic non-biological agents such as ciclosporin, methotrexate and acitretin.

Third line therapy includes systemic biological therapies.

The following agents have been appraised by NICE for the treatment of 'severe psoriasis', defined as exhibiting a Psoriasis Area and Severity Index (PASI) of ≥10 and Dermatology Life quality Index (DLQI) of >10:

- Etanercept (TNFα inhibitor)[1]
- Adalimumab (TNFα inhibitor)[2]
- Ustekinumab (Interleukin 12/23 inhibitor)[3]
- Secukinumab (Interleukin 17A inhibitor)[4]
- Ixekizumab (Interleukin 17A inhibitor)[5]
- Brodalumab (Interleukin 17A receptor antagonist)[6]
- Guselkumab (Interleukin 23 inhibitor)[7]
- Certolizumab pegol (TNFα inhibitor)[8]
- Tildrakizumab (Interleukin 23 inhibitor)[9]
- Risankizumab (Interleukin 23 inhibitor)[10]
- Bimekizumab (Interleukin 17A,17F and 17AF inhibitor)[11]

The following is listed for the treatment of 'very severe psoriasis', defined as exhibiting a PASI ≥20 and DLQI >18:

- Infliximab (TNFα inhibitor)[12]

Assess initial response to biologic therapy in people with psoriasis at time points appropriate for the drug in question, and then on a regular basis during therapy (e.g. every 6 months).[13]

Before initiating or making changes to biologic therapy, take into account both psoriasis and psoriatic arthritis and manage treatment in consultation with a rheumatologist.[13]

Lines of Biologics

Guidance on additional lines of biologic treatment after third line has not been produced by NICE. An advisory statement produced by the Regional Medicines Optimisation Committee states:

> *A policy adopted by a commissioner that would serve to limit patients' access to appropriate treatments based on a number of prior treatments being attempted would be counter to the provisions of the NHS Constitution*[14]

And:

> *When a treatment fails, guidance from specialist bodies suggests switching to a biologic with a new mechanism of action is more effective than switching within class, although it should be noted that this is based on low quality evidence.*[15] *The exception to this is secondary failure of anti-TNF treatment due to formation of anti-drug-antibodies, in which case switching within class may be a valid treatment option*.[14,16]
>
> *In situations where the appropriateness of further treatment options is undecided, a peer multidisciplinary team discussion is likely to be helpful*[14]

Based on these principles, **this guideline supports the use of a total of six lines of biologic treatment**, taking into account the mechanisms of action of the available biologics and accounting for the potential for secondary failure due to anti drug antibodies in the case of anti TNF agents.

Supra-specialist advice from a clinician with expertise in biologic therapy should be sought for treatment **beyond second** line biologic.

Fifth and **sixth** line biologic treatment may be initiated subject to Multi-Disciplinary Team approval at tertiary centre, with agreement from at least 3 consultants, including input from other specialties as required.

Apremilast and Dimethyl Fumarate

Apremilast is a Phosphodiesterase type-4 inhibitor and Dimethyl Fumarate is an oral fumaric acid ester (FAE); both are approved by NICE for the treatment of moderate to severe plaque psoriasis and either may be used where a biologic is considered inappropriate. Use will not be regarded as one of the sequential treatment options in the patient's pathway.

Apremilast and dimethyl fumarate should be used as described in their respective NICE Technology Appraisals.

NICE TA 419[17] and NICE TA475[18] respectively allow Apremilast or Dimethyl fumarate to be used for treating moderate to severe plaque psoriasis in adults whose disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and ultraviolet-A light), or when these treatments are contraindicated or not tolerated, only if:

- the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
- treatment is stopped if the psoriasis has not responded adequately at 16 weeks; an adequate response is defined as:
    - a 75% reduction in the PASI score (PASI 75) from when treatment started or
    - a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from start of treatment

For Apremilast the drug's manufacturer must provide the drug with the discount agreed in the patient access scheme.

REFERENCES

[1] NICE TA103 Etanercept and efalizumab for the treatment of adults with psoriasis. https://www.nice.org.uk/guidance/ta103 [Accessed online on 12 April 2016]

[2] NICE TA146 Adalimumab for the treatment of adults with psoriasis https://www.nice.org.uk/guidance/ta146 [Accessed online on 12 April 2016]

[3] NICE TA180 Ustekinumab for the treatment of adults with moderate to severe psoriasis https://www.nice.org.uk/guidance/ta180 [Accessed online on 12 April 2016]

[4] NICE TA350 Secukinumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta350 [Accessed online on 12 April 2016]

[5] NICE TA442 Ixekizumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta442/resources/ixekizumab-for-treating-moderate-to-severe-plaque-psoriasis-pdf-82604781265093 [Accessed online 27 February 2018]

[6] NICE TA511 Brodalumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta511/resources/brodalumab-for-treating-moderate-to-severe-plaque-psoriasis-pdf-82606774969285 [Accessed online 14 May 2018]

[7] NICE TA521 Guselkumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta521 [Accessed online 16 July 2018]

[8] NICE TA574 Certolizumab pegol for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta574 [Accessed online 25 July 2019]

[9] NICE TA575 Tildrakizumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta575 [Accessed online 25 July 2019]

[10] NICE TA596 Risankizumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta596 [Accessed online 17 September 2019]
[11] NICE TA723 Bimekizumab for treating moderate to severe plaque psoriasis https://www.nice.org.uk/guidance/ta723 [Accessed online 15 July 2022]
[12] NICE TA134 Infliximab for the treatment of adults with psoriasis https://www.nice.org.uk/guidance/ta134 [Accessed online on 12 April 2016]
[13] British Association of Dermatologists, 'Guidelines for biologic therapy for psoriasis 2020: a rapid update', *British Journal of Dermatology*, vol 183, pp 628-637, March 2020
[14] Regional Medicines Optimisation Committee (RMOC) Advisory Statement, Sequential Use of Biologic Medicines Version 2.0. May 2020 https://www.sps.nhs.uk/wp-content/uploads/2020/01/Sequential-use-of-biologic-medicines-RMOC-v-2.0-1.docx [Accessed online on 13 May 2020]
[15] Singh, J. A. et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis: ACR RA Treatment Recommendations. Arthritis Care Res. 68, 1–25 (2016).
[16] Lamb, C. A. et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. Gut 68, s1–s106 (2019).
[17] NICE TA419 Apremilast for treating moderate to severe plaque psoriasis. https://www.nice.org.uk/guidance/ta419 [Accessed online on 13 May 2020]
[18] NICE TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis. https://www.nice.org.uk/guidance/ta475 [Accessed online on 13 May 2020]