This policy statement is approved by Halton, Knowsley, Liverpool, South Sefton, Southport and Formby, St Helens, Warrington, West Lancashire, and Wirral CCGs

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PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
FIRST APC BOARD DATE: 28 MAY 2014
LAST APC BOARD DATE: 28 NOV 2018

NHS
Pan Mersey
Area Prescribing Committee

PSORIATIC ARTHRITIS: sequential use of high cost agents

RED

The Pan Mersey Area Prescribing Committee recommends the sequential use of high cost agents, adalimumab, apremilast▼, certolizumab, etanercept, golimumab, infliximab, ixekizumab▼, secukinumab▼, tofacitinib▼ and ustekinumab in the management of psoriatic arthritis (PsA) in accordance with the recommendations below, and the accompanying flowchart.

The Pan Mersey Area Prescribing Committee recommends that in addition to NICE-approved use in PsA, a second alternative anti-TNF agent (aTNF) can be used in patients who fit the NICE criteria but fail to respond (primary inefficacy or secondary loss of efficacy) to the first aTNF or have side-effects to the first aTNF. If the second aTNF is not tolerated due to side-effects, a third may be tried. In addition ustekinumab is recommended as an option when treatment with an aTNF is contraindicated but would otherwise be considered or the person has had treatment with one or more aTNF, in line with NICE TA340. NICE TA433, NICE TA445, NICE TA537 and NICE TA543 recommend that apremilast, certolizumab and secukinumab, ixekizumab and tofacitinib may be considered in patients not responding to an aTNF or where an aTNF is contra-indicated.

NICE TA199, NICE TA220, NICE TA340, NICE TA433, NICE TA445, NICE TA 537 and NICE TA543 recommend adalimumab, apremilast certolizumab, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab in psoriatic arthritis (PsA) where the following criteria are met:

- The person has peripheral arthritis with three or more tender joints and three or more swollen joints, and
- The psoriatic arthritis has not responded to adequate trials of at least two standard disease-modifying antirheumatic drugs (DMARDs), administered either individually or in combination.
- Treatment is to be discontinued in people whose psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis Response Criteria (PsARC) at 12 weeks. People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks but whose PsARC response does not justify continuation of treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response (see NICE TA103, NICE TA134 and NICE TA146 for guidance on the use of aTNF in psoriasis).
- Apremilast, certolizumab, ixekizumab, secukinumab and tofacitinib are only recommended if supplied as agreed in the patient access scheme.

If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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(or earlier if there is significant new evidence relating to this recommendation)

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EFFECTIVENESS

NICE recommend certolizumab, ixekizumab, secukinumab, or tofacitinib where a patient has not responded to prior aTNF[2-4]. Open label studies and registry data have confirmed the potential benefits of "switching" aTNF therapies in patients with PsA[5-12].

The EULAR (European League against Rheumatism) recommends switching to a second biological agent, including between aTNFs, on loss of efficacy in PsA, based on studies showing good efficacy to a second aTNF and studies of ustekinumab and secukinumab included many patients previously treated with aTNFs[13].

The BSR (British Society for Rheumatology) guidance also recommends switching to an alternative aTNF in the event of failure of the first aTNF in PsA[14].

SAFETY

aTNF are contra-indicated in active tuberculosis or other severe infection, and in Class III or IV heart failure.

Caution should be exercised as aTNF increase risk of infections, and they should be used with caution in patients with history or at increased risk of tuberculosis, hepatitis B, malignancies and lymphoproliferative disorders, skin and other cancers, heart failure, blood dyscrasias, demyelinating disease

Ustekinumab is contra-indicated in clinically important infection. It may cause serious allergic and skin reactions, headache, nasopharyngitis, and upper respiratory tract infection.

Secukinumab is contra-indicated in clinically important infection. It may cause hypersensitivity reactions and exacerbate Crohn's disease.

Tofacitinib is contra-indicated in active tuberculosis and serious or opportunistic infections and severe hepatic impairment.

Ixekizumab is contra-indicated in clinically important active infections.

See individual product SPCs for further details.

COST

Estimated 7.25 patients per year across Pan Mersey area, equivalent to 0.5 per 100,000 population per year.

NICE TA 220 Golimumab psoriatic arthritis costing statement estimates prevalence of people with psoriatic arthritis eligible for treatment as 1448 in England = 3.6 / 100,000 population (54 in Pan Mersey area), of which 1248 would respond, leaving up to 200 = 0.5 / 100,000 population as non-responders to first anti-TNF therapy.

Estimated annual cost of aTNF for these patients is £5,000 / 100,000 population. NICE states there is no significant change in resource impact anticipated specifically from use of certolizumab, ixekizumab, secukinumab or tofacitinib[1-3] and apremilast is cost-saving[1].

PATIENT FACTORS

British Society for Rheumatology and British Health Professionals in Rheumatology rheumatoid arthritis guidelines on safety of anti-TNF therapies 2018 describes recommended monitoring for aTNFs.

See individual product SPCs for further details.

PRESCRIBING INFORMATION See individual product SPCs.

IMPLEMENTATION NOTES Prescribing should be retained by the specialist. Administered (often self-administered) by subcutaneous injection via prefilled syringe (except infliximab administered by intravenous infusion, and apremilast and tofacitinib orally), usually by "home care" arrangement. Patients should be given the special alert card.

REFERENCES

1. NICE TA443. Apremilast for treating active psoriatic arthritis, 2017.
2. NICE TA445. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs. 2017
3. NICE TA537. Ixekizumab for treating active psoriatic arthritis after inadequate response to DMARDs. 2018
4. NICE TA543. Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs. 2018
5. Saad AA, et al. Persistence with anti-tumour necrosis factor therapies in patients with psoriatic arthritis: observational study from the British Society of Rheumatology Biologics Register. Arthritis Res Ther. 2009;11(2):R52
6. Gomez-Reino JJ, Carmona L. Switching TNF antagonists in patients with chronic arthritis: an observational study of 488 patients over a four-year period. Arthritis Research & Therapy 2006;8(1):R29
7. Conti F, et al. Switching tumour necrosis factor alpha antagonists in patients with ankylosing spondylitis and psoriatic arthritis: an observational study over a 5-year period. Ann Rheum Dis 2007;66(10):1393-7
8. Coates LC, et al. Sustained response to long-term biologics and switching in psoriatic arthritis: results from real life experience. Ann Rheum Dis 2008; 67(5):717-9
9. Mazzotta A, et al. Efficacy and safety of etanercept in psoriasis after switching from other treatments: an observational study. Am J Clin Dermatol 2009;10(5):319-24.
10. Papoutsaki M, et al. Adalimumab for severe psoriasis and psoriatic arthritis: an open-label study in 30 patients previously treated with other biologics. Journal of the American Academy of Dermatology 2007;57(2):269-75
11. Spadaro A, et al. Switching from infliximab or etanercept to adalimumab in resistant or intolerant patients with spondyloarthritis: a 4-year study. Rheumatology (Oxford) 2010;49(6):1107-11
12. Fagerli KM, et al. Switching between TNF inhibitors in psoriatic arthritis: data from the NOR-DMARD study. Ann Rheum Dis 2013;72:11 1840-1844
13. Gossec L, , et al. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rheum Dis. 2016;75:499–510
14. Coates LC, et al. The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics. Rheumatology (2013) 52 (10): 1754-175.
15. NICE TA340 Ustekinumab for treating active psoriatic arthritis. June 2015