NHS
Pan Mersey
Area Prescribing Committee

MONOARTHRITIS or OLIGOARTHRITIS, inflammatory: biological agents

The Pan Mersey Area Prescribing Committee recommends the prescribing of biological agents (adalimumab, certolizumab, etanercept, golimumab, infliximab, secukinumab and ustekinumab) by specialists only, for inflammatory monoarthritis or oligoarthritis as specified below.

RED

Patients may be considered for treatment with biological therapy in line with the following:

- Severe inflammatory monoarthritis or oligoarthritis (2 joints) (HLA B27 positive arthritis, reactive arthritis, psoriatic, undifferentiated) involving a large joint or moderately large joint (knee, hip, ankle, shoulder, elbow) despite an adequate trial of two standard DMARDs, appropriate injectable steroids, and NSAIDs. (Adequate trial of DMARD defined as being usually of at least 6 months duration with at least 2 months at standard dose).

- Biological therapy should be reviewed at 3 months to assess efficacy response. In case of adequate response, therapy will continue with 6-monthly re-assessments in rheumatology clinic. In reactive arthritis, biological therapy can be stopped at 6 months of remission. In others, treatment may be continued and clinician can make a decision on tapering and stopping treatment as deemed clinically appropriate.

In case of inadequate response (primary inefficacy), loss of response (secondary inefficacy), or side-effects alternative biological agents may be considered but discontinued if no effect.

- For details of criteria for assessing response and further information refer to accompanying treatment pathway [link]

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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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Effectiveness

Small trials and case series have shown improvement in outcome[1,2] but there is a lack of randomised controlled trials investigating the use of anti-TNF therapies in oligoarthritis[3]. Although the inclusion criteria for most clinical trials could have included patients with 3 or 4 active joints, the vast majority of patients had polyarticular disease with around 20 active joints[3]. The only large randomised controlled trial to give information about the proportion of patients with oligoarticular disease was an adalimumab study[4], where 25% had an oligoarticular presentation at baseline but separate sub-analyses of the efficacy of adalimumab in this cohort are not available. The British Society for Rheumatology recommends that anti-TNF therapies should be considered in patients with severe persistent oligoarthritis (less than 3 tender/3 swollen joints), that has a major demonstrable influence on well-being and who have failed treatment with at least two conventional DMARDs and appropriate intra-articular therapy [3].

Secukimumab proved safe and effective in all psoriatic arthritis domains in a cohort of 608 patients, 27% of whom had mono-oligoarthritis[6]. Ustekinumab efficacy was noted as part of a prospective multicentre study in psoriatic arthritis, where it was noted that the patients with mono-oligoarthritis seem to be favored in reaching an early minimal disease activity, so it may be considered as a predictor of treatment response[7].

Safety

Anti-TNF are contra-indicated in active tuberculosis or other severe infection, and in Class III or IV heart failure. Caution should be exercised as anti-TNF 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 – see individual product SPCs for further details.

Most common side-effects are infection, skin cancer, blood dyscrasias, hypersensitivity, increased lipids, electrolyte disturbances, mood alterations, headache, paraesthesias, visual disturbance, vertigo, tachycardia, hypertension, flushing, breathlessness, cough, GI pain, elevated LFTs, rash, worsening of psoriasis, muscle pain, renal impairment, injection site reaction, oedema and pyrexia. See individual product SPCs for further details.

Secukinumab is contraindicated in clinically important, active infection, e.g. active tuberculosis. Caution should be exercised when considering the use of secukinumab in patients with a chronic infection or a history of recurrent infection. Most common side-effects are respiratory tract infections, oral herpes, tinea pedis, oral candidiasis, otitis externa, neutropenia, headache, conjunctitvitis, rhinorrhoea, diarrhoea, nausea and urticaria.

Ustekinumab is contraindicated in clinically important, active infection. Most common side-effects are respiratory tract infection, nasopharyngitis, sinusitis, cellulitis, dental infections, herpes zoster, , vulvovaginal mycotic infection, hypersensitivity reactions, depression, dizziness, headache, facial palsy, oropharyngeal pain, nasal congestion, diarrhoea, nausea, vomiting, pruritus, pustular psoriasis, skin exfoliation, acne, back pain, myalgia, arthralgia, fatigue and injection site reactions.

See individual product SPCs.

Cost

Costs per 100,000 population in Pan Mersey for anti-TNF: assuming 50% of patients on biosimilar anti-TNF and 50% on alternative anti-TNF at mean cost of alternatives, for 19 patients is £175,000 in Pan Mersey area = £11,150 per 100,000 population. Estimated cost for use of secukinumab and ustekinumab in Pan Mersey increases to £241,000 = £12,700 per 100,000 population per year for 11 patients over the next 5 years.

Actual cost will be lower due to commercial in confidence discounts available.

Patient factors

The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis. Rheumatology, 58 (2), 2019: e3–e42 make monitoring recommendations[5].

Also 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), usually by "home care" arrangement. Patients should be given the special alert card.

References

1. Sakellariou G T et al. Disease-modifying anti-rheumatic drugs for refractory severe knee synovitis in patients with peripheral spondyloarthritis: efficacy and predictors of response Scand J Rheumatol. 2013; 42(5):369-72.
2. Iannone F et al. Two-year survival rates of anti-TNF-α therapy in psoriatic arthritis (PsA) patients with either polyarticular or oligoarticular PsA. Scand J Rheumatol. 2015; 44(3):192-99
3. Coates L.C et al. The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics. Rheumatology 2013; 52(10): 1754-57
4. Mease P.J et al. Adalimumab for the treatment of patients with moderately to severely active psoriatic arthritis: results of a double-blind, randomized, placebo-controlled trial. Arthritis Rheum 2005; 52(10): 3279-89
5. Holroyd C R et al. The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis. Rheumatology, 58 (2), 2019: e3–e42
6. Ramonda R, et al. Effectiveness and safety of secukinumab in 608 patients with psoriatic arthritis in real life: a 24-month prospective, multicentre study. Rheumatic and Musculoskeletal Diseases Open 2021;7:e001519
7. Chimenti MS, et al. Effectiveness and safety of ustekinumab in naïve or TNF-inhibitors failure psoriatic arthritis patients: a 24-month prospective multicentric study. Clin Rheumatol. 2018 Feb;37(2):397-405.