- **Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed (January 2016)**
NICE TA375
Infliximab, in combination with methotrexate, is recommended as an option for treating rheumatoid arthritis, only if the following criteria are met:
  - disease is severe, that is, a disease activity score (DAS28) greater than 5.1, **and**,
  - disease has not responded to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs).

  Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained.

  Patients currently receiving infliximab whose disease does not meet the above criteria should have the option to continue their treatment until they and their clinician consider it appropriate to stop.
www.nice.org.uk/guidance/ta375
- **TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (February 2016)**
NICE TA383
Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended as options for treating severe active ankylosing spondylitis in patients whose disease has responded inadequately to, or who are intolerant of, non-steroidal anti-inflammatory drugs (NSAIDs). Infliximab is recommended only if treatment is started with the least expensive infliximab product. Patients currently receiving infliximab should continue treatment with the same infliximab product until they and their clinician considers it appropriate to stop.

  The response to treatment should be assessed 12 weeks after the start of treatment and should only be continued if there is clear evidence of response.

  Treatment with another tumour necrosis factor (TNF) - alpha inhibitor is recommended in those who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or in those whose disease has stopped responding after an initial response.
www.nice.org.uk/guidance/ta383

● **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Powder for solution for infusion

CAUTIONARY AND ADVISORY LABELS 10

- **Flixabi** (Biogen Idec Ltd) ▼
  Infliximab 100 mg Flixabi 100mg powder for concentrate for solution for infusion vials | 1 vial PoM £377.00 (Hospital only)
- **Inflectra** (Pfizer Ltd)
  Infliximab 100 mg Inflectra 100mg powder for concentrate for solution for infusion vials | 1 vial PoM £377.66 (Hospital only)
- **Remicade** (Merck Sharp & Dohme Ltd)
  Infliximab 100 mg Remicade 100mg powder for concentrate for solution for infusion vials | 1 vial PoM £419.62 (Hospital only)
- **Remsima** (Napp Pharmaceuticals Ltd)
  Infliximab 100 mg Remsima 100mg powder for concentrate for solution for infusion vials | 1 vial PoM £377.66 (Hospital only)
- **Zessly** (Sandoz Ltd) ▼
  Infliximab 100 mg Zessly 100mg powder for concentrate for solution for infusion vials | 1 vial PoM £377.66 (Hospital only)

PHOSPHODIESTERASE TYPE-4 INHIBITORS

Apremilast

14-Jan-2020

● **DRUG ACTION** Apremilast inhibits the activity of phosphodiesterase type-4 (PDE4) which results in suppression of pro-inflammatory mediator synthesis and promotes anti-inflammatory mediators.

● **INDICATIONS AND DOSE**

Active psoriatic arthritis (in combination with disease-modifying antirheumatic drugs or alone) in patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy | Moderate to severe chronic plaque psoriasis that has not responded to standard systemic treatments or photochemotherapy, or when these treatments cannot be used because of intolerance or contra-indications

- BY MOUTH
- Adult: Initially 10 mg daily on day 1, then 10 mg twice daily on day 2, then 10 mg in the morning and 20 mg in the evening on day 3, then 20 mg twice daily on day 4, then 20 mg in the morning and 30 mg in the evening on day 5, then maintenance 30 mg twice daily, doses should be taken approximately 12 hours apart; review treatment if no response within 24 weeks of initiation

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE (JANUARY 2017): APREMILAST (*OTEZLA*®): RISK OF SUICIDAL THOUGHTS AND BEHAVIOUR

A review of evidence from clinical trials and postmarketing cases has suggested a causal association between apremilast and suicidal thoughts and behaviour.

● **CAUTIONS** Concomitant use of drugs likely to cause psychiatric symptoms · history of psychiatric illness · low body-weight—consider discontinuation if weight loss is unexplained or clinically significant

● **INTERACTIONS** → Appendix 1: apremilast

● **SIDE-EFFECTS**

- **Common or very common** Appetite decreased · back pain · cough · depression · diarrhoea · fatigue · gastrointestinal discomfort · gastrointestinal disorders · headaches · increased risk of infection · insomnia · nausea · vomiting
- **Uncommon** Gastrointestinal haemorrhage · rash · suicidal tendencies · weight decreased

● **CONCEPTION AND CONTRACEPTION** Exclude pregnancy before treatment and ensure effective contraception during treatment.

● **PREGNANCY** Avoid—teratogenic in *animal* studies.

● **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.

● **RENAL IMPAIRMENT**

Dose adjustments Reduce dose if eGFR less than 30 mL/minute/1.73 m^2; consult product literature for initial dose titration.

● **MONITORING REQUIREMENTS**

- Manufacturer advises monitor body-weight regularly in patients underweight at the start of treatment.
- Manufacturer advises monitor for psychiatric symptoms (including depression, suicidal ideation and behaviour)—discontinue treatment if new or worsening psychiatric symptoms are identified.

● **PATIENT AND CARER ADVICE** Manufacturer advises patients and carers should be instructed to notify the prescriber of any changes in behaviour or mood, and of any suicidal ideation.