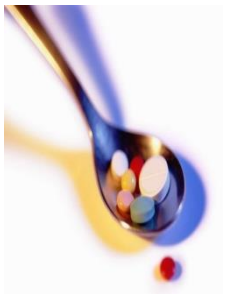

GMMMG
Greater Manchester
Medicines Management Group
NHS

NewTherapiesSubgroup

April 2015

Apremilast (Otezla®▼) for the treatment of moderate to severe chronic plaque psoriasis and for the treatment of active psoriatic arthritis in adults.

The New Therapies Subgroup discussed the above at its meeting on 21st April 2015. The recommendation of this subgroup is as follows:*

The New Therapies Subgroup of the GMMMG considered the use of apremilast for the treatment of moderate to severe chronic plaque psoriasis in adult patients who have failed to respond, have a contraindication, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA) and for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to previous DMARD therapy.

The group recommends the use of apremilast in those patients that have failed conventional systemic therapy but are not eligible for treatment with a biologic due to contraindications and/or potential safety concerns.

Apremilast was found to be superior to placebo for the endpoint of 75% reduction in Psoriasis Area Severity Index (PASI) and there is some evidence apremilast has comparable efficacy to etanercept however this has yet to be fully published. There is emerging evidence that shows that apremilast may be of benefit in those patients who suffer from both psoriasis and psoriatic arthritis.
At £7,150 per patient per annum, apremilast is more expensive than conventional systemic therapies, but is cheaper than the biologics and has the advantage of being an oral preparation so will not require admission to hospital for administration. However initiation of apremilast and ongoing monitoring should remain with specialists within secondary/tertiary care settings. Patient access schemes may be available for some therapies used for moderate to severe plaque psoriasis which CCGs and Trusts can take advantage of that may further reduce costs to the health economy.

According to set criteria apremilast was found to be a high priority for funding within the specific patient group recommended.

Review date: April 2016

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

Further information / commissioning implications for CCGs

Apremilast is a Payment by Results [PbRe] drug exclusion and so commissioners will be recharged its costs by Trusts. Data for the first 5 months of this financial year is presented below for ustekinumab which has a similar marketing authorisation:

Recommendation

The drug will be an additional treatment option in patients unsuitable for biologics and so is likely to increase costs in this area. However, it may displace more unpleasant treatments such as coal tar and those without a UK marketing authorisation such as fumaric acid esters [Fumaderm®]. *Prescribing Outlook* [PO] cost calculator suggests:
An estimated 1% of patients (14 per 100,000) have severe disease and are eligible for biological therapy. If the cost of apremilast is assumed to be similar to that of biologicals, then its use would not be expected to have any significant impact on drug costs during the first year. There may however be additional future costs as it represents an additional treatment option, and depending on the license may also be an option for patients failing anti-TNF treatment.
For use in psoriatic arthritis, PO suggests:
If it is assumed that:
- treatment with apremilast will cost £7,500 per patient per year and
- it is used prior to anti-TNF agents (ranging from 0.5 to 1.5 people per 100,000 population) i.e. as an additional treatment step, this could result in an additional cost implication of around £4,000 to £11,000 per 100,000 population.

Formulary and Interface considerations

Despite Prescribing Outlook suggesting that while the drug would be started in Secondary Care but would be continued in Primary Care, the Consultant with whom we worked in producing this recommendation suggested that it would not be suitable for transfer of prescribing to GPs.

Should the drug receive a positive NICE Technology Appraisal, it will be automatically included in the GM Formulary. NICE guidance was expected in October and while a negative Final Appraisal Determination for its use in moderate to severe plaque psoriasis was issued at the beginning of September, this has been appealed, final guidance has not been issued and there is now no date for the issue of guidance. Similarly to the psoriasis situation, NICE's initial proposals for use in psoriatic arthritis have been appealed and there is no expected date for issue of guidance. Should positive guidance be issued, the authors of the current GM pathways in these therapeutic areas will then need to consider its place.

Summary of Impact

Although a high priority for funding in a selected patient group, it is likely to have a relatively low impact within the overall £335M PbRe spend within GM, although if usage approached the higher end of PO estimates, that would equate to a further £2.6m on this bill.