25th March 2014

**Agomelatine (Valdoxan®▼) for the treatment of major depressive episodes in adults.**

The New Therapies Subgroup discussed the above drug at a meeting on the 25th March 2014. The recommendation of this subgroup is as follows:*  

The New Therapies Subgroup of the GMMMG considered the use of agomelatine for the treatment of major depressive episodes in adults.

The group does not recommend the use of agomelatine (Valdoxan®▼) for the above indication.

Clinical trial data although promising shows that efficacy of agomelatine only reached clinical significance (as per NICE criterion\(^1\)) in trials involving extremely depressed (HAMD score > 28) patients, and this was due to a decrease in the response to placebo rather than an increase in the response to the medication. In addition, reports of several serious cases of hepatotoxicity limit its use.

Agomelatine may have a role for specialist initiation but only in those patients with severe depression who have already failed on all classes of antidepressant therapies. LFTs should be performed in all those receiving agomelatine. Agomelatine should not be prescribed to the elderly (>75).

The group would also like to draw attention to the NICE statement on why a submission to NICE wasn’t made for agomelatine. The manufacturer did not submit as the majority of the clinical trial evidence for agomelatine was for first-line treatment and furthermore, was not against the full range of comparators used in practice; therefore an economic case proving cost effectiveness could not be put forward.

According to set criteria agomelatine was deemed to be a low priority for funding.

\(^1\) NICE considers a weighted mean between-group difference of at least three points or a standardised mean difference of at least 0.5 in the Hamilton Depression (HAMD) rating scores to demonstrate clinical efficacy.

Review date: March 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* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.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.

NOT TO BE USED FOR COMMERCIAL OR MARKETING PURPOSES
Further Information for CCGs

Current use

Due to a previous low priority recommendation, use is already limited.

NTS Recommendation

The recommendation reinforces the previous status as a low priority for funding.

Future commissioning implications

There are not expected to be any future financial or commissioning implications as cost per month is not dissimilar to other branded antidepressants. The greatest cost-driver is the volume of specialist referral and additional blood test monitoring.

Formulary and Interface considerations

The drug is not in the Greater Manchester Formulary, nor on the Do Not Prescribe list. It has a small place in therapy. The drug has a RAG status of amber and thus should be initiated in Secondary Care; a Shared Care Protocol should accompany any request to a GP for a transfer of prescribing.

Summary of impact

Pattern of usage suggests low use although relatively higher take up in two Mental Health Trusts indicating specialist preferences. Prescribing and outpatient attendances should be monitored to ensure appropriate levels of usage.