

New Medicines Subgroup: Process for terminated, suspended and withdrawn NICE TAs

Cheshire and Merseyside Area Prescribing Group (APG)

Ordinarily, a grey RAG rating or grey statement will be issued at the point of drug launch. If the drug and indication is in the NICE Technology Appraisal (TA) work programme then this grey position will not be reviewed until the NICE TA is published as per the agreed NMSG processes.

There have previously been drugs/indications that were in the NICE TA work programme, but subsequently the NICE TA was terminated or suspended. There has also been an event in which NICE has withdrawn a TA.

Terminated TAs

In circumstances where the NICE TA has been terminated and the manufacturer has confirmed that there is unlikely to be sufficient evidence that using that drug to treat that indication is cost-effective use of NHS resources, or that they do not intend to launch the drug to treat that indication in the UK, the NMSG should not look to assess this drug/indication further. The drug for this indication should become BLACK in the formulary, with a link to the terminated NICE TA, and that it would not be reviewed further unless NICE recommences the TA process and a further NICE TA is published.

Suspended TAs - Non-launched drugs

Suspended NICE TAs differ from terminated NICE TAs as a final decision has not been provided by NICE. For circumstances where drugs have not yet launched and the NICE TA is suspended, the NMSG will monitor and revisit at the point of launch or when the NICE TA is updated.

Suspended TAs - Launched drugs

For a launched drug, a grey RAG rating / statement awaiting publication of the NICE TA will already be available in the formulary. Launched drugs with a suspended NICE TA remain as GREY in the formulary and monitored. If a grey statement has been produced, additional wording should be added:

“NICE have currently suspended the TA for this drug/indication. Therefore, this recommendation will be reviewed when further information is available on the NICE website.”

However, at the point which the TA becomes terminated, the agreed process for terminated NICE TAs would apply and the RAG rating would be changed from GREY to BLACK.

Withdrawn TAs

Each withdrawn TA would need to be reviewed on a case by case basis. However, where a NICE TA is withdrawn due to withdrawal of a product license by the manufacturer there will be insufficient evidence to recommend its use within the NHS and the NMSG proposes that the drug/indication becomes BLACK in the formulary with a link to the withdrawn TA.