



NICE rejects daratumumab (darzalex) for use second-line with bortezomib and dexamethasone



Fiona Chaplin | Jul 17, 2018

Janssen's multiple myeloma (MM) drug, daratumumab (Darzalex), has made waves in MM treatment, showing huge promise as a monotherapy as well as in combination with commonly used backbone regimens, at all stages of the disease. Following data from the [CASTOR clinical trial](#), daratumumab was granted approval by the [European Medicines Agency](#) (EMA) for use alongside bortezomib and dexamethasone, for the treatment of MM patients that have received one prior therapy. It was hoped that the [National Institute for Health and Care Excellence](#) (NICE) would follow suit, but on 12 July 2018 cost regulators announced their decision to rule against full approval of this combination for the treatment of patients in England and Wales.

This decision was made on the basis that the data is not yet mature enough to enable a full cost-effectiveness analysis. Regulators have said that the current data is immature and they would like to wait for data from the long-term analysis, and also to see comparative data for alternative second-line options such as carfilzomib plus dexamethasone.

Currently, the NICE guidelines do not enable patients to receive any triple combinations as a second line therapy, despite mounting evidence that 'three is better than two'. Janssen has pledged to work with both NICE and NHS England to help overturn this decision.

Following a wealth of data presented at ASH 2017, it was commented that 'everything is better with daratumumab'. However, whilst patients in England and Wales can now access daratumumab as a monotherapy fourth line, they will have to wait for daratumumab combos a little while longer.

References:

1. http://www.pharmatimes.com/news/nice_turns_down_darzalex_combo_for_pre-treated_multiple_myelo
2. <https://pharmaphorum.com/news/nice-rejects-darzalex-citing-lack-clinical-evidence/>

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