Belfast Health and Social Care Trust
caring supporting improving together

FOI/31112

22 April 2024

TA663 NICE Policy

- **How many patients have been treated under the TA663 NICE policy, to date?**
- **Were they referred by another NI Health Trust that does not offer a direct intervention cancer treatment/service within their infrastructure?**
- **How many patients from each Trust?**
- **How many patients tolerated and received the full and recommended 400mg daily dose?**
- **How many patients had to receive a titrated lower dose below the daily 400mg daily recommendation?**
- **How many patients were placed on each of the 100mg, 200mg, 300mg daily schedules?**
- **How many patients had their treatment schedule lowered due to neutropenia?**
- **For those on the lower dose schedules: what was the median weekly average amount of Venetoclax each patient received? (Please only total weeks after and do not include the weekly ramp-up/lead-in period of initial drug titration 20/50/100/200 mg), including only the remaining 41 weeks of treatment whereby Ventoclax is recommended to be taken. In effect, allowing for treatment breaks and pauses how many weeks out of the 41 weeks beyond drug 'ramp-up' was each patient considered to be actively taking Venetoclax treatment, what median weekly drug exposure did this provide?**
- **For those on lower dose schedules: for how long in total was each patient given a Venetoclax treatment break over the 45 week period when Venetoclax is expected to be taken?**
- **How many patients had their treatment supported with the use of G-CSF/ Filgrastim?**
- **Did any patients fail to complete the full 48-week treatment plan? Why/on what medical grounds? How many patients?**
- **What age range of patients were treated under NICE TA663? What was the median age of the patients that received treatment?**
- **Were any patients treated beyond the 48-week timeframe as laid out by the NICE TA663 Managed Access Agreement/NI Managed Entry process and the SmPC license? If so, to what extent?**
- **Would this extension to treatment be considered 'off-label'?**
- **Or was it done following a permitted treatment break under the terms of the Managed Access Agreement, i.e. stopping treatment longer than 6 weeks with use of an approval form for e.g. covid, then restarting?**
- **In any instance were a treatment break approval form was used, how long did the break in treatment last?**

The information requested is not collated centrally and an extensive trawl of patient notes would be required. We estimate that compliance with this request for information would exceed the appropriate costs limit. Under Section 12 of the Freedom of Information 2000, the limit has been specified as £450 and represents the estimated cost of one or more persons spending 18 hours in determining whether we hold the information, locating, retrieving and extracting this information.

- **Were any patients provided with a test to establish uMRD status during or post-treatment? How many patients?**
  No, uMRD testing is not commissioned in Northern Ireland.
- **What type of test in each case was provided**? N/A
- **At what point during or after treatment was the test conducted**? N/A
- **What general 'end of treatment/ finalised information or patient data' is supplied by the treating clinician/hospital team and is expected to be returned to the drug company Abbvie that supplies these drugs?** None
- **How soon during treatment and at what points after the completion of treatment is that data relayed to Abbvie?** N/A