Southern Health and Social Care Trust

Information Governance Team

FOI 2384

2nd August 2024

FREEDOM OF INFORMATION ACT 2000 – INFORMATION REQUEST

Request:

Q1. How many patients have been treated under the TA663 NICE policy, to date?

Response Q1:

<5

The Trust has a legal duty to protect patient confidentiality, in line with this duty the figure <5 has been provided where figures are very low. This is because of the potential risk of identification of an individual. In reaching this decision the Trust has taken into account the small geographical area which the Trust serves. In addition the Trust has taken into account the fact that all information disclosed in response to an FOI is disclosed to the 'world at large' and is published on the Trust website.

S 40 (2) (third party information) of the Freedom of Information Act 2000 has been applied to exempt the redacted information from disclosure. The Trust does not consider the disclosure of the redacted information to be fair to the individuals concerned as there is the potential risk of identification of an individual(s) which they would not expect, and which would therefore breach the fairness element of the first principle of the Data Protection Act 2018.

Q2. Were they referred by another NI Health Trust that does not offer a direct intervention cancer treatment/service within their infrastructure?

Response Q2:

Information not known

Q3. How many patients from each Trust?

Response Q3:

N/A, as above

Q4.How many patients tolerated and received the full and recommended 400mg daily dose?

Response Q4:

<5

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Q5. How many patients had to receive a titrated lower dose below the daily 400mg daily recommendation?

Response Q5:

None

Q6. How many patients were placed on each of the 100mg, 200mg, 300mg daily schedules?

Response Q6:

None – except as step-up, not for ongoing therapy

Q7. How many patients had their treatment schedule lowered due to neutropenia?

Response Q7:

None

Q8. 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?

Response Q8:

No-one to date on lower dose schedules

Q9. 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?

Response Q9:

N/A

Q10. How many patients had their treatment supported with the use of G-CSF/ Filgrastim?

Response Q10:

None

Q11. Did any patients fail to complete the full 48-week treatment plan? Why/on what medical grounds? How many patients?

Response Q11:

None to date.

Q12. What age range of patients were treated under NICE TA663? What was the median age of the patients that received treatment?

Response Q12:

All over 65 years

Q13.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?

Response Q13:

None

Q14. Would this extension to treatment be considered 'off-label'?

Response Q14:

.N/A

Q15. 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?

Response Q15:

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N/A

Q16.In any instance were a treatment break approval form was used, how long did the break in treatment last?

Response Q16:

No break

Q17. Were any patients provided with a test to establish uMRD status during or post-treatment? How many patients?

Response Q17:

We do not do bone marrow biopsies during or after treatment. Haematology response is monitored by checking White Cell counts, Lymphocytes and Lymph nodes through bloods and diagnostic exams. All patients received this.

Q18. What type of test in each case was provided?

Response Q18:

Blood tests, clinical examinations and radiology investigations

Q19.At what point during or after treatment was the test conducted?

Response Q19:

Throughout treatment and pre & post-cycle. CT done mid-way and end of treatment.

Q20.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?

Response Q20:

None

Q21.How soon during treatment and at what points after the completion of treatment is that data relayed to Abbvie?

Response Q21:

N/A

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