Reference:	FOI.2513.20
Subject:	Use of biologics
Date of Request:	11 February 2020

Requested:

1) Is the branded biosimilar AMGEVITA listed on your formulary? Please detail which specialisms use AMGEVITA - Rheumatology, Dermatology, Gastroenterology.

2) Please complete the number of patients prescribed with the following products in the last 12 months within the Rheumatology, Dermatology and Gastroenterology departments:

*How many patients receive the listed therapies as a first or second treatment once they reach the biologic/biosimilar part of their treatment pathway. For example, according to the NICE Pathway, psoriasis patients should receive topical therapy, then systemic non-biological therapy, then systemic biological therapy. We would like to know which therapies are received first and second in the biological therapy part of the pathway.

3) Please answer the table below in response to questions a) and b):

a) Are any local guidelines followed that recommend earlier use of anti-TNF biologics/ biosimilars in the treatment pathway?
b) Are there occasions where patients can receive adalimumab outside of NICE/SMC/ AWMSG/National criteria?

Question	Department					
	Dermatology	Rheumatology			Gastroenterology	
	Psoriasis	Psoriatic arthritis	Rheumatoid arthritis	Ankylosing spondylitis	Crohn's disease	Ulcerative colitis
a)						
b)						

4) What is the contractual agreement for seeing and treating patients with anti-TNF biologics between you and your referring CCGs/Health Boards?

Contractual agreement	Yes/No
Block contracts	
Fixed price on a patient-by-patient basis	

Response:

1) Yes, AMGEVITA is listed on Hywel Dda University Health Board's (UHB) formulary, but is not used specifically for one speciality. However, the UHB is currently using AMGEVITA firstline for Dermatology and Gastroenterology and second line for Rheumatology.

2) The UHB is unable to provide you with the number of patients who were prescribed the below named biosimilar or biologic products as a first or second line treatment, as it is estimated that the cost of answering your request would exceed the "appropriate level" as stated in the Freedom of Information (Fees and Appropriate Limit) Regulations 2004. The "appropriate level"

represents the estimated cost of one person spending 18 hours or (2 ½ working days) in determining whether the UHB holds the information, and locating, retrieving and extracting the information.

In order to provide you with the number of patients who were prescribed the products as a first or second line for each specialism, the UHB would be required to trace each of the patients prescribed the products and conduct a manual trawl of their records to identify the status of their prescription. It is estimated that conducting the search would cost:

285 patients @ 15 minutes per patient record = 71.25 hours
71.25 hours @ £25 per hours = £1,781.25

The UHB is therefore applying an exemption under Section 12 of the Freedom of Information Act 2000, which provides an exemption from a public authority's obligation to comply with a request for information where the cost of compliance is estimated to exceed the *appropriate limit*.

Under section 16 of the Freedom of Information Act 2000, the UHB has an obligation to provide advice and assistance. The UHB has therefore provided the total number of patients prescribed the named products within the requested timeframe per specialism.

Product Name	Rheumatology	Dermatology	Gastroenterology
AMGEVITA	*	49	52
HUMIRA	12	*	56
HYRIMOZ	0	0	0
IMRALDI	110	*	0

Where the figures in the table have been replaced with an asterisk (*), the UHB is unable to provide you with the exact number of patients due to the low numbers of cases (5 and under), as there is a potential risk of identifying individuals if this was disclosed. The UHB is therefore withholding this detail under Section 40(2) of the Freedom of Information Act 2000. This information is protected by the Data Protection Act (DPA) 2018 / General Data Protection Regulations (GDPR) 2016, as its disclosure would constitute unfair and unlawful processing and would be contrary to the principles and articles 6 and 9 of the GDPR. This exemption is absolute and therefore there is no requirement to apply the public interest test.

In reaching this decision, the Data Protection Act 2018 / General Data Protection Regulations 2016 defines personal data as data which relates to a living individual who can be identified solely from that data or from that data and other information which is in the possession of the data controller.

3) a) No, the UHB does not follow any local guidelines that recommend earlier use of anti-TNF (tumor necrosis factor) biologics or biosimilars in the treatment pathway.

b) Yes, patients can received Adalimumab outside of the specified National Institute for Health Care and Excellence (NICE) criteria following a successful Individual Patient Funding Request (IPFR) application.

4) The stated contractual agreements for seeing and treating patients with anti-TNF biologics are not applicable within NHS Wales.