Cancer Vanguard

Service Impact Research Study

Background:

Biosimilars are approved by the EMA if they are shown to be equivalent to their reference molecule in terms of safety, efficacy and quality. Due to the differences in their development program, biosimilars are able to be marketed at a cost significantly less than their reference product. To understand the impact of the reduced drug acquisition cost on total expenditure for that given treatment, it is necessary to fully characterise the areas of expenditure from vial to patient both prior to and after a decision to use a biosimilar has been made. This must account for one-off costs associated with implementing biosimilar usage, such as additional patient counselling requirements and also evaluate the impact of this biosimilar implementation on outcome measures such as patient satisfaction.

Hypothesis H_A:

Biosimilar use has a net reduction on overall expenditure compared to their reference molecule and has no impact on patient satisfaction measures

Aim:

To fully characterise total costs and services associated with delivery of a cancer treatment with a biosimilar equivalent and re-evaluate once a biosimilar is in use.

Methods:

Assess associated costs in terms of the following factors as detailed below.

Items highlighted in green require prospective consideration and need input prior to the adoption of the biosimilar

	Evaluate before biosimilar introduction		Evaluate after biosimilar introduction	
1. Eligible patients	Task	Time frame	Task	Time frame
a. Total number of patients prescribed biologic under review	✓	For one month	✓	Monthly for first quarter, then quarterly for first year
i. Patients on IV and SC	✓		✓	
ii. Patients eligible for biosimilar usage according to Trust policy (all patients without indication protected by patent or research protocol)	✓		✓	
iii. Patients receiving biosimilar			✓	
b. Clinical trial patients on biologic under review				
i. Patients on commercial stock	✓		✓	
ii. Patients on sponsor funded trial stock	✓		✓	
iii. Patients receiving biosimilar			✓	
2. Drug acquisition costs				
a. Drug cost (actual spend- vial cost or mg costs)	✓	For one month	✓	Monthly for first quarter, then quarterly for first year
b. Service delivery model i. % (near patient vs. SC vs. compounder (3rd party) vs. aseptic vs. at home) ii. Costs (near patient vs. compounder (3rd party) vs. aseptic vs. at home)	✓ Do you expect this model to change as a result of using a biosimilar?		✓ Did this model change as a result of using a biosimilar?	

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c. Costs associated with additional stock storage and risk minimisation activities			✓	
d. Wastage (vial wastage, expired or unused infusions etc.)	✓ Do you perceive there being any wastage in your system?		✓	
e. Do you use dose banding?				
3. Service costs				
a. Counsel +/- consent patients	✓	Across 20 sequential patients	✓	Across 20 sequential patients in first and second month of use
b. Preparation of patient materials and education			✓	
c. Time associated with clerking patient	✓		✓	
d. Administration costs i. Chair time (Vs. total capacity) ii. Monitoring	✓ Is monitoring or chair time requirement expected to change?		✓ Did monitoring or chair time change?	
e. Resources associated with ensuring reimbursement from commissioners	✓ Do you anticipate use of biosimilars changing your reimbursement process?		✓	
f. Costs associated with prescribing or administration errors			✓	
4. Costs associated with biosimilar introduction				
a. Preparation and validation of aseptic worksheet			✓	One-off measurement and calculation
b. Preparation for formulary application			✓	
c. Development/adaption of biosimilar policy and guidance			✓	
d. Development and delivery of patient focused and staff educational material			✓	
e. Costs of further education of staff (initial and ongoing)			✓	
f. Updating electronic prescribing and dispensing software			✓	
g. Costs due to lack of stability data/validated method			✓	
h. Costs associated with changes to prescribing activities and uncertainty			✓	
5. Patient satisfaction survey				
a. Costs to perform patient satisfaction survey	✓	100 patients in same month as1 and 2	✓	100 patients in same month as 1 and 2
b. Assessment of patient global satisfaction with treatment	✓		✓	