GUIDE TO GE3:

HOSPITAL MEDICINES OPTIMISATION

Biosimilars Monoclonal Antibodies
Implementation Resource Pack

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EXECUTIVE SUMMARY

NHS England supports the appropriate use of biosimilars to drive greater competition and release cost efficiencies to support the treatment of an increasing number of cancer patients and the uptake of new and innovative medicines.

The European Medicines Agency (EMA) has licensed the first biosimilar of rituximab, Truxima, and stock of this product has been available since March 2017, ema.europa.eu.

'Hospital Trusts are required to implement biosimilar rituximab in Q2 2017, for the purposes of CQUIN GE3, however Trusts can choose to implement Truxima before then.'

NHS England expects that Trusts who have not signed up for the Hospital Medicines Optimisation CQUIN GE3 to still meet the same targets for implementation that are in the CQUIN GE3 under a Service Delivery Implementation Plan (SDIP).

INTRODUCTION

This document aims to demystify the commissioning of cancer medicines and support hospitals looking to undertake NHS England's Commissioning for Quality and Innovation (CQUIN) for medicines optimisation, which includes the implementation of biosimilar monoclonal antibodies.

We have adopted a similar style to that of the popular 'Guides' series.

These guides aim to provide an understanding of complex and important topics, for example they proved very useful for understanding complex operating systems. Therefore we have adopted the same approach to help bring clarity to NHS commissioning and support those needing to 'optimise' their use of medicines and in particular implement biosimilar monoclonal antibodies (MABs) such as rituximab.

WHO IS THIS GUIDE FOR?

This document will be useful for anyone wishing to improve their understanding of how commissioning in the NHS works and is particularly useful for hospital staff in England involved in having to deliver the Hospital Medicines Optimisation CQUIN and introduce biosimilar MABs into practice.

Hospitals that are not undertaking the CQUIN scheme will still have to implement biosimilar MABs, therefore the advice contained in this document is relevant and adoptable.

The relationship between hospital providers and commissioners in Scotland, Wales and Northern Ireland is different to England and advising on this is outside the scope of this document, however the advice on implementing biosimilar MABs should be relevant to all home nations.

This guide will be useful for the hospital pharmacy teams, managers and clinical staff involved in medicines optimisation and biosimilar MABs implementation; as well as their project team members, for example those in the finance directorate reporting back to NHS England.

HOW TO USE THIS GUIDE

We will use symbols to help clarify and explain key points or to highlight what action is needed.

IDEA		Makes a suggestion or idea of how to tackle a challenge
STICKY POINT		Caution as will need to be careful to avoid getting stuck at this point
BACKGROUND READING		Provides background information that can be read at a later date
TEAM APPROACH		Highlights the need for a *team or project team* approach to tackling a challenge

The document is deliberately written in a friendly non-technical style but inevitably we will have to use jargon so we also include a helpful Glossary – see pages 25 & 26 – to explain terms used in the document.

WHAT IS IN THIS DOCUMENT?

DISCLAIMER

The guide has been prepared with the advice of commissioning specialists and aims to give an overview (not the exact details) of the processes involved in commissioning and what is needed to implement biosimilar MABs as part of tackling the NHS England 2017/19 Hospital Medicines Optimisation CQUIN: GE3.

It is not an official guide and there may be differences between the general advice given in this guide and actual local practice. Similarly there may be other approaches to deliver the CQUINS targets and implement biosimilar MABs not described in this document. Therefore readers are strongly advised to ensure they communicate with their local commissioning teams to understand local processes.

SECTION 1: START AT THE BEGINNING: WHAT IS A CQUIN?

The first questions to be addressed are what is a CQUIN and why is the specific Hospital Medicines Optimisation CQUIN GE3 for 2017/18 and 2018/19 important?

NHS England States '*The Commissioning for Quality and Innovation (CQUIN) framework supports improvements in the quality of services and the creation of new, improved patterns of care.*'

CQUINS are a tool used by commissioners to encourage best practice and efficiency in provision of the services they commission, which includes use of medicines.

The theory is the most efficient services that deliver the best care for patients are also likely to be those that are least wasteful and most cost-effective.

To find out more about CQUIN schemes visit:
https://www.england.nhs.uk/wp-content/uploads/2016/11/pss-cquin-guide-nov16.pdf

NHS England wishes to encourage hospitals to review practices and how they deliver services to become more efficient, benefiting patients and saving money for the NHS as a whole.

However, NHS England also recognises it sometimes needs to incentivise hospitals to carry out the additional work required to change the services they provide as this additional work takes time and is associated with staffing costs, which is where a CQUIN scheme kicks in.

A CQUIN provides financial incentives for hospitals to make changes and undertake work to reconfigure services. That is, if they successfully complete a CQUIN the hospital can save money for the commissioner, therefore the commissioner will pay the hospital a fixed amount of money. The money that is paid from the commissioner is usually a small percentage of the overall monies that the commissioner pays them and this can be a percentage of their high cost drugs bill or a percentage of their overall annual contract with NHS England.

The total amount a hospital provider can earn from a CQUIN is fixed, so that this limits the number of CQUINs that can be signed up for. For most acute hospital providers the total CQUIN payment value can be up to 2.0% of their contract value with NHS England (Acute hospitals that are Hepatitis C Network Lead Providers have a higher total CQUIN value, 2.5%).

WHAT ARE THE TYPES OF CQUIN SCHEMES?

Some CQUIN schemes apply across acute or mental health services, but many including the medicines optimisation scheme are specific to one of the services or areas that NHS England commissions.

Schemes for 'Prescribed Specialist Services' commissioned nationally by NHS England are developed through the relevant National Clinical Reference Groups (CRGs). Thereby clinical leaders shape schemes from the expertise in their service. See section 3 below - Demystifying Commissioning.

It is worth understanding how CQUIN schemes are chosen and who is involved in deciding what schemes your own organisation signs up for - this will usually be a senior manager involved in contract setting with NHS England.

SECTION 2: UNDERSTANDING THE CQUIN GE3

(Hint) It's Not Just About Biosimilars

GE3: Hospital Medicines Optimisation CQUIN scheme is part of the specialised services CQUIN scheme and is multi-year, designed for implementation over two years.

The GE3 CQUIN scheme can be found at:
https://www.england.nhs.uk/nhs-standard-contract/cquin/pres-cquin-17-19/

THE GOAL: To optimise use of high cost drugs, tackle variation and reduce waste by incentivising:

- Adoption of biosimilars and generics
- Improved drug data quality
- Utilising most cost-efficient dispensing channels
- Compliance with policies/guidelines to reduce variation and waste

THE RATIONALE: The Carter Review highlighted that unwarranted variation in the use and management of medicines costs the NHS at least £0.8 billion that could be reinvested.

THE REWARD: A target payment which is 1.0% of relevant high-cost drug expenditure.

It's a good idea to find out more about the Carter Review and Hospital Medicines Optimisation. This is useful even if you are not looking at implementing the GE3 CQUIN as all hospitals must have a Carter transformation plan, therefore understanding 'Carter' and 'Medicines Optimisation' is important.

See https://www.gov.uk/government/publications/productivity-in-nhs-hospitals

The CQUIN is a large document full of jargon and spilt into key sections – this Guide goes through each key section with particular focus on what needs to be done to meet each CQUIN trigger.

Section A summarises what the scheme is trying to achieve and **Section B** provides contract specific information, which is completed following local contract discussions. **Section C** is the Scheme Specification Guide, which is probably the key section, but also one of the most difficult to read! **Section D** is the Scheme Justification, which actually provides a lot of information - perhaps should be read first?

We will explore the document in greater detail, focusing on the triggers.

Section C scheme specification guide, is one of the most difficult to read!

The key to understanding it is to know:

- There are five different work streams ***called triggers 1 to 5*** to be tackled, each with its own targets which have to be achieved
- There is a table of specific evidence that has to be provided to commissioners to show the triggers are being met, i.e. that the hospital is delivering
- There are definitions and descriptions on how the evidence is described and presented
- There is a timescale of what evidence is needed by each quarter and also how far through (%) in delivering a trigger each quarter is acceptable

SECTION 3: DEMYSTIFYING COMMISSIONING

Before we unpick the CQUIN it is useful to have some background understanding of commissioning as the CQUIN uses jargon and assumes everyone is an expert in NHS England commissioning processes.

This section will focus on how specialised commissioning in England works and how hospitals in England get paid for cancer medicines.

NHS ENGLAND COMMISSIONING POSITION ON BIOSIMILAR MABS

One key point to understand is the implementation of biosimilars MABs is a key NHS target and NHS England will be expecting Trusts to deliver on implementation of these medicines. The 2017/18 NHS England commissioning intentions document* states:

'In order to allow NHS England to continue to invest in new developments we will require all Hospitals to use more cost effective generic and biosimilar products where these are available and in line with product licenses. We expect Hospitals to have an active improvement programme to implement use of these products with all new patients being initiated on the biosimilar/ generic product within 3 months of them becoming available and all existing patients to have been moved to the biosimilar/ generic product within 12 months.'

**Available at https://www.england.nhs.uk/wp-content/uploads/2015/12/spec-comm-intent.pdf*

NHS England circulated a commissioning letter SCC1734 dated 11th April 2017 (available on request from local NHS England teams) which advised that 'NHS England does not require Trusts to implement biosimilar rituximab until Q2 at the earliest for the purposes of the CQUIN. However Trusts can choose to implement Truxima before then.'

HOW CONTRACTING AND COMMISSIONING WORKS

The commissioner for cancer medicines and chemotherapy services in England is NHS England. Nationally, NHS England commissions specialised services, primary care, some public health services, offender healthcare and some services for the armed forces.

One anomaly is that chemotherapy is part of specialised commissioning, but chemotherapy is delivered in all providers so is not strictly a specialised service. It is part of specialised commissioning because of the high burden of cost of cancer medicines and the need to have a single commissioner to ensure access is uniform across England and there is no postcode variation.

NHS England Specialised Services is responsible for commissioning the procurement and delivery of chemotherapy, including drug costs and molecular diagnostic testing for targeted medicines.

To see exactly what is commissioned for cancer: Look at 'The Manual' – this is a technical document describing the 149 prescribed specialised services, Adult Cancer which includes chemotherapy can be found on page 228.

https://www.england.nhs.uk/commissioning/spec-services/key-docs/

So called 'routine services' are commissioned by local CCG clinical commissioning groups, not NHS England. Exploration of how CCG commissioning works is going beyond the scope of this document, however the National Audit Office document linked below includes some useful background reading, see https://www.nao.org.uk/wp-content/uploads/2016/04/The-commissioning-of-specialised-services-in-the-NHS.pdf

NHS ENGLAND STRUCTURE

NHS England has four regional teams yet is one single organisation operating to a common model with one board.

- North of England regional team
- Midlands and East of England regional team
- London regional team
- South of England regional team

The specialised commissioning teams cover a range of portfolios that have been grouped into six National Programmes of Care (NPC), of which cancer is one. The NPCs have a board and are supported by a number of Clinical Reference Groups (CRGs) where commissioners gain advice and support from clinical experts. The two key CRG's with respect to GE3 are the Chemotherapy CRG and the Medicines Optimisation CRG.

Each year NHS England publishes its Commissioning Intentions. This is a key document that provides the basis for engagement between NHS England and providers of specialised services, to inform business plans and inform contracts. The Commissioning Intentions are intended to *'drive improved outcomes for patients, and transform the design and delivery of care, within the resources available'.* In other words the document tries to ensure high standards of service for patients, whilst being as cost effective as possible.

There is a lot of detailed information in the Commissioning Intentions – the trick is knowing where to look and to interpret what the statements mean to the local contracting arrangements. So knowing your commissioners and how local contract works is a good idea.

KNOWING YOUR COMMISSIONERS

Each regional team has a number of local offices that contain specialised commissioning teams who work with their provider hospitals. There are 10 local specialised commissioning 'hubs'. The local hub is responsible for monitoring and agreeing local contracts. Every hospital will have a locally agreed contract with its NHS England local specialised commissioning hub for the specialist services that it provides.

Specialised commissioning teams will consist of contract managers, service specialised commissioners and finance managers supported by the commissioning pharmacist and often a part time cancer pharmacist. The role of specialist commissioning is to monitor contracts with local NHS provider organisations and track spending on the services that NHS England commissions, which include high cost excluded medicines.

NHS England Commissioning Pharmacists are a good link and involved in local medicines issues. The hospital chief pharmacist will know who the local NHS England Pharmacist is or you can navigate through NHS England regional team's website to find your local office telephone number and ask for their email. See https://www.england.nhs.uk/about/regional-area-teams/

ANNUAL COMMISSIONING AND QUARTERLY MONITORING MEETINGS

Exact local arrangements may vary but in general the contracting discussions follow a similar format. NHS England local hub specialised commissioning team sits down to agree the contract prior to the financial year with a team from each hospital, which usually includes senior managers and finance leads (who will have sought advice appropriate form clinical services leads).

The financial contract has to be agreed by both parties, the financial contract will outline what a Trust will get paid by NHS England for the specialist services that it delivers. As part of agreeing this overall contract the hospital has to commit to delivering the services according to NHS England's service specifications contracts; and the hospital has the opportunity to choose to participate in a number of CQUIN schemes.

Once the contract has been agreed there will be quarterly monitoring meetings between the hospital and NHS England teams, who will review

- The overall performance against financial targets
- Actual spend versus predicted spend on all high cost excluded drugs
- Performance against each CQUIN scheme

The quarterly contracting meeting is where hospitals have to provide evidence and show that they have met the targets in the CQUIN scheme, therefore it is important to recognise that there is a quarterly cycle of providing information and knowing how to report that information is a fundamental requirement.

MONITORING MEDICINES SPEND: BLUETEQ, SACT AND MINIMUM DATASET

Most hospital drug spend is funded as part of an overall package agreed between hospitals and commissioners. However in the case of specialised commissioning certain high cost drugs are specifically 'excluded' from the overall package of care and hospitals send an individually itemised bill to NHS England for these drugs. In theory this allows the commissioner to know exactly how much drug has been used for individual patients.

NHS England has three tools at its disposal for monitoring spend of high cost excluded medicines; the information that comes with the 'bills' from providers – the Minimum Dataset (MDS), the Blueteq system and SACT data.

BLUETEQ

For Cancer Drug Fund (CDF) and all new NICE funded cancer medicines any doctor wanting to prescribe these drugs has to register with an electronic web-based pre-approval system called Blueteq, before treatment is started. This gives the commissioner information on every patient who starts on the drug and ensures drugs are only used for approved indications.

Doctors prescribing cancer medicines are responsible for registering patients on blueteq. Members of the local hospital pharmacy teams will check registration before preparing medicines. The blueteq portal for CDF and NICE cancer medicines can be found at http://www.blueteq.com/CDF

Top tip – you need an nhs.net email address to access blueteq

The SACT dataset and the Minimum Dataset both feature as targets for the GE3 and are discussed in more detail in later sections.

SECTION 4: THE CQUIN TRIGGER TARGETS

TRIGGER 1: ADOPTION OF BEST VALUE GENERIC/BIOLOGIC PRODUCTS

This Trigger target is designed to ensure that the NHS achieves best value in adoption of generic/ biologic products over the next two years. The CQUIN gives a list of 23 different drugs where there are savings to be made from switching to generic supplier and from actively monitoring market developments, such as the launch of biosimilar products and moving patients to the most cost effective treatment.

This trigger accounts for 33% of the CQUINS payment.

GENERIC SWITCHES

Switching to generic medicines as they become available to ensure savings is standard practice within the NHS so there should be little or no additional work required to meet this part of trigger one.

Pharmacy departments will have to be mindful of when generics are due to become available, and reduce stock holding so patients can be rapidly substituted onto the generic.

There should not need to be any additional work in informing patients and prescribers of the switch to generic medicines.

BIOLOGICAL AND BIOSIMILARS

The CQUIN requires that 90% of new patients must receive the biosimilar within one quarter of guidance on its use being made available from NHS England. The guidance will be issued in the form of a Specialised Commissioning Circular (SCC) letter sent via email to key contacts in the hospital, usually the lead clinician, chief pharmacist and medicines director.

The adoption of the biosimilar monoclonal antibodies rituximab for lymphomas and trastuzumab for breast cancer will be key to delivering the majority of the savings in this trigger.

(*Note* if originator molecules reduce in price to match biosimilars' price these can be adopted).

Adoption of biosimilars is not as easy as generic medicines as biosimilar MABs are biological medicines that are developed to be highly similar to an existing biological medicine. They undergo comprehensive regulatory approval to demonstrate comparability to an existing biological medicine. Like all biological medicines they are subject to pharmacovigilance monitoring, e.g. batch number tracking and must be prescribed by brand name.

The British Oncology Pharmacy Association (BOPA) has produced comprehensive implementation guidance on biosimilar monoclonal antibodies (MABs). The BOPA document describes the evidence, recommendations and practical considerations for adoption of biosimilar MABs and gives advice on switching.

See http://www.bopawebsite.org/publications/position-statements

The Cancer Vanguard or 'vanguard' sites have produced guidance and resources to support the implementation of biosimilars.

See http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/

Patients already on originator molecules cannot be automatically substituted to the biosimilar. They have to undergo a managed switch programme involving their clinicial team.

As well as starting new patients on biosimilars/generics the CQUIN requires that 80% of applicable existing patients should be switched to a biosimilar within one year, except if standard treatment course is < 6 months.

The financial split of Trigger 1 payment between new and existing patients should be proportional to spend forecast, absent the CQUIN for each group.

Section 5 gives a comprehensive example action plan for adopting biosimilar rituximab.

TRIGGER 2: MINIMUM DATA SET (MDS)

Improving data quality associated with high cost drugs remains a priority for NHS England, Trigger 2 of the CQUINS requires hospitals to:

'Improve drugs MDS data quality to include dm+d as drug code in line with ISB 0052 by June 2017 or in line with agreed pharmacy system upgrade as well as all other mandatory fields. All hospitals submit HCD data in agreed MDS format fully, accurately populated on a monthly basis and bottom line matches value for drugs on ACM'

SO WHAT DOES ALL OF THIS ACTUALLY MEAN?

It's all about data, data fields, data formats and data transfer standards – with lots of jargon… dm+d….MDS…. ACM….etc to confuse us

Firstly the standard drugs minimum dataset (MDS) was only introduced in 2016/17 and it defined the data fields hospitals needed to include when sending bills for high cost excluded drugs (HCD) to NHS England. The data sent in the MDS is part of what is known as the Aggregate Contract Monitoring (ACM) standard file format; again this is another standard for data transfer.

The format and population of MDS has not been fully adopted by provider hospitals. Consequently it is proving difficult for NHS England to validate accurate payments; therefore improving the MDS is included in the CQUIN.

The good news is this is a one off exercise and many hospitals may well be close to compliance; for others it may mean more work.

One way of looking at it is to think of the minimum dataset as the information a hospital has to put on its invoices to get the money back for the drugs it has used. In terms of financial flow it's worth clarifying that hospitals buy drugs at the approved price (including discounts agreed by the NHS in the form of patient access schemes) from manufacturers or wholesalers and charge this price back to NHS England.

It is not enough for a hospital to simply send a bill saying we spent £20,000 on Drug X last month, please give us the money back! Before NHS England will pay for high cost drugs it wants to know patient level details; disease treatment codes and a variety of other data fields contained in the minimum dataset.

Why? The fact that NHS England Specialised Services spends £2.4billion a year on high cost drugs (HCDs) means getting payment right is important!

You can find all the MDS codes on the Specialised Services reporting requirements website: https://www.england.nhs.uk/nhs-standard-contract/ss-reporting/ See *'Patient level drug dataset specification for 2017/18'*

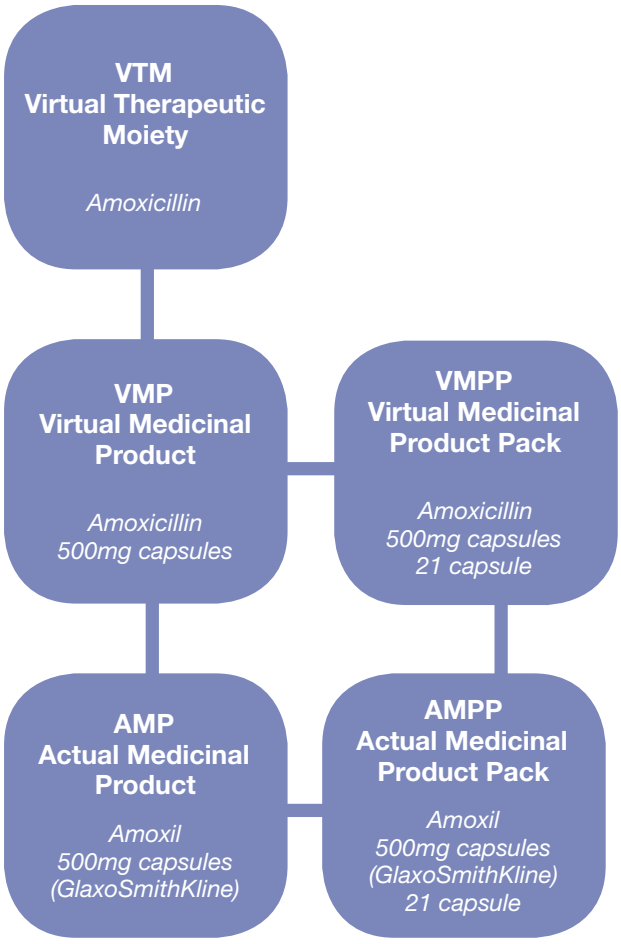
COMPLIANCE WITH MDS DATA

The MDS involves extracting data from pharmacy systems, patient administration systems and finance systems and then using the information to populate the MDS. Improving the MDS data should be a one off exercise; one key factor is the compliance of the hospitals pharmacy system to output dm+d data. This has to be done by June 2017 and may require a pharmacy system upgrade. There are 30 fields in the MDS, though provision of the dm+d code provides 7 codes.

What's in a name?

How drugs are named is important, commissioners want to know the precise name of the drug, drug strength, unit size and supplier as these all affect the price. The NHS standard for identifying drugs is called the **dictionary of medicines and devices' (dm+d)** identifier.

This dictionary contains unique identifiers and associated textual descriptions for all medicines and medical devices so the specific medicinal product used is known.



The diagram opposite shows the components of the dm+d codes. *Source: 'Information Standard Board ISB 0052 dm+d specification'*[2].

ISB 0052 is the standard document that defines how dm+d codes are formatted. It is needed when information about medicines used in the care of a NHS patient is transferred electronically from one system to another system, to ensure all systems can output and receive it accurately.

By improving drugs MDS data quality to include dm+d identifier from all providers NHS England will be able to ensure it is paying the correct price for medicines and hospitals are not overcharging. MDS data is at its simplest the data from the hospital pharmacy stock management system put into the correct format before it goes to NHS England (usually via a monthly spread sheet).

Trigger 2 accounts for 17% of the value of the CQUIN; to meet the targets of Trigger 2 a team approach is needed.

You will need your pharmacy procurement and systems expert, the finance manager who works with pharmacy and hospital patient information/database experts to ensure the systems are in place to capture the MDS fields.

It's vital that pharmacy staff have a good relationship with finance staff.

Meeting the MDS is expected to be achieved in year one (17/18), with the evidence being the commissioners examining the MDS submissions in months 10- 12 (January 2018 – March 2018) to ensure the MDS is fully and accurately populated. The commissioners recognise that a pharmacy systems upgrade many be needed and have accounted for this in the time line.

One factor that needs to be considered is the pharmacy staff time that will be needed each month on an on-going basis to check the data quality from the pharmacy system, e.g. to remove double entries when stock is booked out and returned before the MDS is submitted.

Protect time each month to ensure adherence and help to safeguard achieving Trigger 2

TRIGGER 3: COST-EFFECTIVE DISPENSING ROUTES

The key to understanding Trigger 3 lies in section D1.

'Evidence and Rationale for Inclusion' of the CQUIN, which discusses the findings and recommendations of the Carter Report.

Lord Carter's review of efficiency in hospitals shows how the NHS can make significant savings. The Carter report and associated documents can be found at https://www.gov.uk/government/publications/productivity-in-nhs-hospitals

NHS England wants to increase the use of cost effective dispensing routes for outpatient medicines recommended in the Carter Report. '*Trusts that have not currently outsourced their outpatient dispensing services should ensure their HPTP (Hospital Pharmacy Transformation Programme) plans include a review of these services and have a plan in place for improving productivity and efficiency, including consideration of alternative supply routes, such as homecare providers or community pharmacies.'*

It is up to 20% cheaper to provide medicines in primary care

Hospitals have to pay VAT at 20% when dispensing medicines, but medicines dispensed and issued in primary care have zero-rated VAT, i.e. 20% cheaper.

This means there a large potential savings to be made by moving dispensing of high cost medicines out of hospitals. In reality, providers of outsourced dispensing will charge hospitals a fee for the service thus reducing the potential savings.

NHS England Commissioning intentions states '*Providers are expected to ensure VAT efficient dispensing methods (e.g. outsourced pharmacies, homecare etc.) are used where clinically appropriate in order to ensure maximum cost efficiencies and to align with the recommendation from the Carter Review to consider alternative supply routes.'*

ACHIEVING TRIGGER 3

The Carter Review requires all hospitals to agree a HPTP (Hospital Pharmacy Transformation Programme) and have plans in place by April 2017 to ensure hospital pharmacies achieve their targets. Reviewing dispensing routes is part of the HPTP plan, therefore achieving the first part of the Trigger which is preparing a transition plan should have already been done.

This needs to be submitted to commissioners at the end of Quarter 1 (April to June 17) for approval.

The commissioners will then agree a target % for the volume of dispensing to be delivered through the most effective dispensing route.

It is worth noting that the dispensing in the hospital pharmacy may actually be the most effective route, depending on charges for primary care/home dispensing; in which case as long as this can be demonstrated the CQUIN will be met.

The most likely scenario is that there will be a number of high cost medicines that can be more effectively provided by homecare/home delivery or community dispensing. The local NHS England Commissioning pharmacist is the key contact in looking into this as they will be aware of the most cost effective options.

YEAR ONE AND YEAR TWO TARGETS

Achieving this Trigger is worth 33% of the CQUIN in both year one and year two. It will be monitored based on the % of agreed medicines that can be supplied via the agreed cost effective dispensing routes at the designated cost per item tariffs. This means that hospitals through negotiation with local commissioners have some control and can agree the targets that the CQUIN Trigger is monitored on.

COLLABORATION BETWEEN HOSPITAL ASEPTIC PREPARATION UNITS

One further factor that feeds into Trigger 3 is for hospitals to identify the true value and scale of the opportunity for rationalisation and integration of hospital pharmacy procurement and production; developing an NHS Manufactured Medicines Product Catalogue and possibly moving towards a local area/regional model for these services. This is beyond the scope of an individual hospital's CQUIN submission, but you should be aware of any work being undertaken regionally and your hospital should be willing to discuss any recommendations for regional aseptic centralisation.

HOMECARE

Consideration of homecare and/or home delivery of high cost oral medicines must form part of the transformation plan.

NATIONAL COST PER ITEM

Whilst not part of meeting the CQUIN in the past hospitals have benefited from patient access scheme rebates and % gain sharing agreements for drugs supplied through homecare. Hospital providers were able to undertake a local deal with commissioners for recompense for the work to outsource drug from a community provider, e.g. homecare, and save money on zero-rated VAT. This 'gain-share' of the savings with NHS England has now been replaced by the Cost Per Item approach to recompense Trusts for work and/or activity to achieve savings. Thus ensuring consistent reimbursement across providers.

It's quite clear that any savings Hospitals make in procuring drugs must be passed on entirety to the Commissioner.

Commissioners will only pay for the cost of the drugs.

Tariff Payments for delivery and preparation of chemotherapy

One question that comes out of consideration of the commissioner only paying the cost of drugs to the provider is in relation to chemotherapy, *"What about the administration of the drug and preparation of the drug – how is that funded?"* There is a separate payment mechanisms for these known as Tariff, for example in chemotherapy delivery there is a tariff to deliver IV chemotherapy which is approximately £299[3] and is paid for every episode of chemotherapy that is given (the fee for the first cycle may be higher or lower depending on complexity). There is also a locally negotiated fee for every chemotherapy dose that is prepared by pharmacy aseptic units; this fee varies but is around £40-£60 for each aseptically prepared item or £10-20 for the supply of a ready-made syringe/bag for dose banding.

TRIGGER 4: IMPROVING SACT AND OTHER DATASET QUALITY

Trigger 4 requires that '*All hospitals submit required outcomes data (SACT, IvIg) in agreed format fully, accurately populated in agreed timescales*.' This means understanding the current data quality of the hospitals submission to these two national databases, SACT and IvIg, identifying any gaps and agreeing a transition plan for increasing data quality. Compliance with the SACT database is mandated with chemotherapy electronic prescribing systems (which all Trusts are required to have and must be fully implemented by April 2017 (adults) proving it is crucial to extracting the data needed for SACT.

WHAT IS SACT

The Systemic Anti-Cancer Therapy (SACT) dataset is the national mandatory collection of information on chemotherapy and targeted therapy regimen used by all NHS England chemotherapy providers.

For example a person with breast cancer comes into hospital to have the second cycle of a regimen called FEC for which she will have three-weekly treatment with fluorouracil, epirubicin and cyclophosphamide. The provider hospital has to record a variety of information fields for this treatment episode that form the SACT dataset. Every month the data from every patient that has had chemotherapy is sent electronically to a central NHS secure server (SACT portal) run by Public Health England. All hospitals' data are compiled in a national secure database.

The SACT portal is only available on the NHS N3 network, therefore you must be in NHS premises when accessing SACT. http://www.chemodataset.nhs.uk/secure/

The SACT dataset consists of 6 sections: with 42 fields of information from each episode of chemotherapy given to individual patients.

The Sections are:

SECTION 1	Demographics & Consultant
SECTION 2	Clinical Status
SECTION 3	Programme & Regimen
SECTION 4	Cycle
SECTION 5	Drug Details
SECTION 6	Outcome

Of the 42 data fields, 9 are mandatory; that is without this data element the technical process (i.e. submission of the data set) cannot be completed. The remaining 32 fields are still required, with only one optional field, a person's weight.

In each hospital there is a data manager and a chemotherapy lead, usually a clinician or senior pharmacist who accesses the web based SACT portal to upload and check the Trusts submissions each month.

These people should work with the chemotherapy prescribing system leads and service manager to examine their SACT data completeness reports and develop a plan to improve SACT as needed.

SACT LIMITATIONS

What provider hospitals unfortunately cannot do is directly query the SACT database to ask specific questions about their own information. There are only standardised report formats that Public Health England's team has prepared that can be accessed via the web portal.
The SACT team will look at the data for trends and will ask hospitals for more information and to check potentially controversial data before it is published in the public domain.

One of the issues with the SACT data is that of the 42 fields many of them are not always complete, so improving data completeness with SACT is an important feature of the CQUIN.

IG DATABASE

This database monitors the use of immunoglobulin (IvIg) in the NHS.
See http://www.igd.nhs.uk/, like SACT you have to be connected to the NHS N3 network to access the database. The database was instigated after a shortage of immunoglobulin prompted the Department of Health to develop a demand management programme to ensure supply is maintained. NHS England funds immunoglobulin as one of its pass through high costs medicines so is able to compare the data on IvIg use submitted to the national database by Trusts with drug spend/usage information.

Improving compliance will need the pharmacy team to monitor and track all IvIg use each month and ensure database entries have been completed before sending the bills to NHS England. This needs to be an on-going process.

CONCLUSION

We hope this document has demystified the commissioning process and helped understanding for hospitals seeking to 'optimise' their use of medicines and in particular implement biosimilar monoclonal antibodies (MABs) such as rituximab. The NHS is a constantly evolving environment, so it is worth establishing a relationship with your local commissioning pharmacist who can keep you abreast of any changes and developments in commissioning that you need to be aware of.

SECTION 5: ACTION PLANS FOR IMPLEMENTING CQUIN CHANGES

IMPLEMENTATION PLAN FOR BIOSIMILARS

Example Biosimilar Rituximab

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8 +
Identify local pharmacy and clinician champions to take the lead in the introduction of biosimilar rituximab	■							
Arrange preliminary discussion with local NHS Commissioners and/or procurement specialists to understand timelines for switch, commissioning and tendering	■	■						
Identify which indications biosimilar rituximab will be used in, i.e. licensed indications or all indications extrapolated from the off-label use of MabThera		■						
Identify all current patients receiving rituximab infusion (via electronic prescribing system)		■	■					
Identify key stakeholders, for example: consultant haematologists who will be prescribing biosimilars, any patient support groups, nurse specialists and pharmacists		■	■					
Provide information/education to key stakeholders about biosimilars, the EMA licensing, equivalence and the manufacturing process (including intra-product manufacturing changes for both biological medicines and their biosimilars) to ensure confidence in prescribing biosimilars		■	■	■				
Review workload in changing electronic prescribing system and review how system will manage branded prescribing of biosimilar brand alongside MabThera. Allow 2-3 days for completing this system change over and time afterwards for user testing			■	■				
Discuss hospital switch strategy with key stakeholders, identify pharmacy time needed to support switching and impact on clinical pathways				■	■			
Undertake initial financial analysis to identify local spend and set up tracking if signed up for Hospital Medicines Optimisation CQUIN GE3. Note monthly reporting to NHS England	■	■	■	■	■	■	■	■
Agree metrics to be collected during and after the introduction of biosimilars				■	■			
Agree approach to switching, e.g. all patients, patients with more than 50% of course remaining				■	■			

APPENDIX 1 CONTINUED

Example Biosimilar Rituximab Implementation

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8 +
Agree implementation plan for new patients and approach to switching, e.g. all patients, patients with more than 50%, or >3 months of course remaining, staggered approach, etc								
Prepare/co-ordinate use of appropriate patient information/communication on switch to biosimilar rituximab								
Agree approach with nursing staff to manage ward/day unit capacity implications of changing patients undergoing 'rapid rituximab' infusion, e.g. a staggered approach								
Update local chemotherapy protocols and prepare switching guidance for staff								
Set up a kick-off meeting for prescribers, pharmacists and nursing staff to understand support needed to facilitate switch								
When products are launched and local contracts awarded liaise with manufacturers to see what support their product specialists (reps) can provide								
Discussion and implementation of novel delivery strategies, e.g. homecare etc								
Implement agreed switching programme								
Monitor uptake of biosimilar rituximab								
Review and dissemination of learning from initiative. Sharing best practice								

GLOSSARY

ACM **Aggregate Contract Monitoring**	Aggregate Contract Monitoring (ACM) is a standard file format for providers to use when submitting reports to specialised commissioners. This will enable the interchange, in a uniform and consistent format, of monthly aggregate contract monitoring.
dm+d **dictionary of medicines and devices**	The NHS data standard for identifying drugs is called the dictionary of medicines and devices' (dm+d) identifier. It contains unique identifiers and associated textual descriptions all for medicines and medical devices, so the specific medicinal product used is known. This includes the name of the drug, the strength, unit size and the supplier.
Commissioning Intentions	A document produced annually that provides notice to healthcare providers and partners about changes and planned developments in commissioning and delivery of prescribed specialised services.
CQUIN Scheme [1]	Is a locally agreed package of quality improvement goals and indicators, which in total, if achieved, enables the provider to earn its full CQUIN payment.
CQUIN Goal [1]	Describes a quality improvement objective which is being incentivised through the CQUIN scheme, e.g. ***Faster adoption of prioritised best value medicines (biosimilars) as they become available.*** A goal may be measured using one or more indicators (see below).
CQUIN Indicator [1]	Is a measure which determines whether the goal or an element of the goal has been achieved, and on the basis of which payment is made, e.g. ***'Adoption of best value generic/ biologic products in 90% of new patients within one quarter of guidance being made available.'*** The achievement of one indicator should not be dependent on the achievement of a separate indicator within the scheme.
CRGs **Clinical Reference Groups**	Groups of clinicians, commissioners, public health experts, patients and carers use their specific knowledge and expertise to advise NHS England on the best ways that specialised services should be provided. There are 42 Clinical Reference Groups.

GLOSSARY CONTINUED

MDS	The MDS is the standard drugs minimum dataset which defined the data fields hospitals needed to include when sending bills for high cost excluded drugs to NHS England.
HPTP **Hospital Pharmacy Transformation Programme**	A plan produced by hospital pharmacy department which shows its progress towards achieving the recommendations of Lord Carter's review of efficiency within the NHS.
High Cost Excluded Drugs **Or** **Pass through drugs**	NHS England funds high cost drugs, including chemotherapy separately to in addition to the national price for the related service, i.e. providers purchase these drugs and when they are used (issued to patients) their cost is charged to NHS England who in effect rebate the hospital. As long as the drugs are used for their approved indication NHS England has to pay. These are sometimes known as pass through drugs.
Prescribed Services **Or** **Specialist Services**	The specialist services commissioned nationally by NHS England that are 'prescribed in legislation.' Chemotherapy is one of the specialised services commissioned by NHS England under the wider remit of Specialist Cancer Services (adults).
SDIP **Service Development and Improvement Plan**	A Service Development and Improvement Plan allow the commissioner and provider to record action(s) which the provider will take, or which the parties will take jointly, to deliver specific improvements to the services commissioned. An SDIP is about developing an aspect of the services beyond the currently agreed standard.

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