Biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology

Commissioning guide
Implementing NICE guidance

December 2011 (update)
Biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology

This commissioning guide provides support for the local implementation of NICE guidance through commissioning, and is a resource for people involved in commissioning health and social care services in England. Although this guide focuses on commissioning biologic drugs for the treatment of inflammatory disease, commissioners should also be aware that they may need to commission biologic drugs for a range of other conditions such as asthma, multiple sclerosis and some cancers.

This commissioning guide should be read together with the following NICE guidance:

- NICE technology appraisals for biologic drugs for the treatment of inflammatory disease. See list in figure 1
- NICE clinical guideline CG79. Rheumatoid arthritis: the management of rheumatoid arthritis in adults

NICE guidance provides evidence-based recommendations about clinically effective and cost-effective treatments and interventions to improve outcomes for local populations. Commissioners should refer to the original guidance for detailed information about the recommendations and selection criteria for each biologic drug and condition. Commissioners should also note that when a NICE technology appraisal recommends use of a drug or treatment, or other technology, the NHS must usually provide funding and resources for it within 3 months of the guidance being published.

Making commissioning decisions based on NICE guidance and accredited information from NHS Evidence can help commissioners to use their resources more effectively.

This commissioning guide highlights any recommendations supporting cases for disinvestment or decommissioning of services by identifying treatments and interventions that do not add value, enabling commissioners to release resources or generate savings where appropriate.

Implementation of the guidance noted above is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement this guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in the guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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*a* A non-exhaustive list of examples includes omalizumab for the treatment of uncontrolled asthma (TA133), natalizumab for the treatment of multiple sclerosis (TA127) and rituximab for the treatment of non-Hodgkin’s lymphoma (TA65), follicular lymphoma (TA110) and follicular non-Hodgkin’s lymphoma (TA137).
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The guide:

- facilitates the commissioning of biologic drugs for the treatment of inflammatory disease
- specifies service requirements
- helps you determine local service levels
- helps you ensure corporate and quality assurance.

The full text of this commissioning guide can be downloaded or accessed from the navigation menu on the right hand side of the screen. Download the openly available commissioning and benchmarking tool, there is no need to register.

We are keen to improve the commissioning guides in order to better meet the needs of commissioners. Please send us your ideas for future topic-specific guides or other comments.

Read the NICE disclaimer for information on the use and accuracy of content on the NICE website.

- Topic-specific Advisory Group: biologic drugs

December 2011

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**Figure 1: Published NICE technology appraisals for biologic drugs for the treatment of inflammatory disease**

The following is a list of relevant NICE technology appraisals for biologic drugs for the treatment of inflammatory disease, current at August 2011. Please check the NICE website for any subsequent guidance.

- **TA35**: Guidance on the use of etanercept for the treatment of juvenile idiopathic arthritis
- **TA103**: Etanercept and efalizumab for the treatment of adults with psoriasis
- **TA130**: Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis
- **TA134**: Infliximab for the treatment of adults with psoriasis
- **TA140**: Infliximab for subacute manifestations of ulcerative colitis
- **TA143**: Adalimumab, etanercept and infliximab for ankylosing spondylitis
- **TA146**: Adalimumab for the treatment of adults with psoriasis
- **TA163**: Infliximab for acute exacerbations of ulcerative colitis
- **TA180**: Ustekinumab for the treatment of adults with moderate to severe psoriasis
- **TA186**: Certolizumab pegol for the treatment of rheumatoid arthritis
- **TA187**: Infliximab (review) and adalimumab for the treatment of Crohn’s disease
- **TA195**: Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor
- **TA 198**: Tocilizumab for the treatment of rheumatoid arthritis
- **TA 199**: Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis
- **TA220**: Golimumab for the treatment of psoriatic arthritis
- **TA233**: Golimumab for the treatment of ankylosing spondylitis
- **TA234**: Abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs
- **TA238**: Tocilizumab for the treatment of systemic juvenile idiopathic arthritis

NICE has also produced a commissioning algorithm for each condition as a tool to aid the implementation of NICE guidance on biologic drugs for the treatment of inflammatory disease:

- **Rheumatoid arthritis commissioning algorithm**
- **Juvenile idiopathic arthritis commissioning algorithm**
- **Ankylosing spondylitis commissioning algorithm**
- **Psoriatic arthritis commissioning algorithm**
- **Plaque psoriasis commissioning algorithm**
- **Crohn’s disease commissioning algorithm**
- **Ulcerative colitis commissioning algorithm**

NHS Evidence has accredited the process used by NICE to produce guides for commissioners. Accreditation is valid for 5 years from November 2011 and applies to guidance produced since November 2008 using the processes described in ‘Process manual for developing guides from NICE for commissioners: Information for internal NICE teams’ (2011). More information on accreditation can be viewed at www.evidence.nhs.uk
Commissioning biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology

In the past ten years, biologic drugs\(^b\) have emerged as an important advance in the treatment of inflammatory disease such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis plaque psoriasis, Crohn’s disease and ulcerative colitis. These are chronic conditions which can cause pain, debilitation, loss of independence and premature mortality\(^{[4][5][6]}\). These conditions may have a detrimental impact on a person’s quality of life and place a significant financial burden on society – for example, one-third of patients with rheumatoid arthritis stop working within 2 years of diagnosis\(^{[5]}\).

NICE guidance makes recommendations about the use of biologic drugs based on clinical and cost-effectiveness. Biologic drugs are typically recommended for the treatment of patients with an active, and moderate or severe form of their inflammatory condition, and who have contraindications to or whose condition is not responding to conventional treatments and/or pharmacotherapy (please refer to the recommendations in the original guidance). Conventional treatments vary depending on the condition, but commonly include corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) or disease-modifying immunosuppressant drugs, often used in combination.

Where conventional treatments become ineffective for the treatment of rheumatoid arthritis, biologic drugs may slow the destruction of joints, reduce inflammation, slow disease progression or induce full remission\(^{[5][7][8]}\). In dermatology and gastroenterology biologic drugs may suppress disease activity, improve the patient’s condition and provide sustained clinical disease remission\(^{[9][10][11]}\).

On average biologic drugs cost around £9500 per patient per year, compared with around £450 per year for conventional therapy\(^c\). Because of their high cost and specialised nature they are excluded from Payment by Results.

In 2007–8, expenditure on biologic drugs for the treatment of rheumatoid arthritis alone ranged between £0.8 and £3.5 million per acute trust.

\(^b\) The term ‘biologic’ describes treatments developed and produced in live cell systems, which mimic the effects of substances made naturally by the body’s immune system\(^{[1][2]}\). Biologic drugs contain monoclonal antibodies and soluble receptors that specifically modify the disease process, by blocking key protein messenger molecules (for example cytokines such as tumour necrosis factor alpha (TNF-\(\alpha\)) or an interleukin, or cells (such as B- or T-lymphocytes))\(^{[3]}\). The drugs may also be referred to as biological drugs, biologic therapies, biologic interventions, or cytokine modulators. At a first glance these drugs are used for apparently unrelated conditions. However, research has shown that all of these inflammatory diseases have common cytokine disregulation factors\(^{[2]}\).

\(^c\) The average annual cost of conventional therapy is derived from the average annual cost per patient of methotrexate, sulfasalazine, hydroxychloroquine sulphate, leflunomide, azathioprine, gold and penicillamine listed in the British National Formulary 59 (March 2010). The average annual cost of a biologic therapy is calculated from the average costs of adalimumab, etanercept, abatacept and infliximab as detailed in the costing report for TA195 Rheumatoid arthritis – drugs for the treatment after the failure of a TNF inhibitor and TA198 – Rheumatoid arthritis – tocilizumab: costing template (where the cost per patient per year ranges from £8846 to £10,771).
Expenditure on biologic drugs accounts for the highest pharmaceutical spend within some trusts\(^5\). The unrestricted and inappropriate use of biologic drugs could place a large financial burden on the NHS.

The National Audit Office asserts that 14\% of acute trusts are not able to provide biologic drugs for the treatment of rheumatoid arthritis to all patients who qualify for them in accordance with NICE criteria\(^5\). Funding is known to be an obstacle to prescribing biologic drugs for eligible patients, and 30\% of professionals feel restrained by primary care trusts (PCTs) ‘capping’ expenditure on biologic drugs\(^1\)\(^2\). Other constraints in rheumatology services include a lack of nurse specialist resource and staff or day-case facilities\(^5\). Similarly 40\% of UK psoriasis services cite funding as a significant obstacle to prescribing biologic drugs\(^4\).

Effective commissioning and clinical governance of biologic drugs has the potential to contribute to efficiency savings within the care pathway. For example, earlier initiation and better long-term care of patients may help to prevent or reduce costly exacerbations of the disease, hospital admissions and surgical interventions\(^5\)\(^1\)\(^1\).

**Benefits**

The potential benefits of robustly commissioning biologic drugs for the treatment of inflammatory disease include:

- **improving clinical outcomes and the quality of life** for patients with inflammatory disease
- **ensuring that the drugs are prescribed and delivered in a safe environment** by trained and competent staff
- **improving integrated systems for prescribing and administering biologic drugs to patients** across several pathways including rheumatology, dermatology and gastroenterology
- **reducing local and regional inequalities** and improving timely access to treatment with biologic drugs
- **preventing unnecessary costs** through effective commissioning and delivery of biologic drugs, improving patient outcomes and reducing the need for hospital visits and surgical interventions\(^5\)\(^1\)\(^1\)
- **increasing patient choice and improving clinical pathways**, resulting in more efficient care pathways for patients and care closer to home
- **increasing clinical and cost effectiveness.** By making commissioning decisions based on NICE guidance and accredited information from NHS Evidence, commissioners can ensure that they are using their resources more effectively.
**Key clinical issues**

Key clinical issues in providing biologic drugs for the treatment of inflammatory disease include:

- **providing the best possible outcomes** for individual patients and their carers
- **ensuring that all eligible patients are identified** promptly and prescribed biologic drugs in accordance with the relevant NICE technology appraisal(s)
- **providing transparent and equitable care** to all patients requiring biologic drugs
- **identifying exceptional patients** and ensuring that systems are in place that allow them to be considered for treatment with biologic drugs
- **managing risk and ensuring the safe and effective delivery** of biologic drugs to patients in the appropriate setting and in accordance with NICE guidance and local clinical governance arrangements
- **ensuring that the multidisciplinary team are skilled and competent** to prescribe and deliver biologic drugs and monitor their effects on the patient across different specialities and settings
- **ensuring robust monitoring and recording procedures are in place**
- **providing a quality assured service**.

**National drivers**

National priorities and initiatives relevant to commissioning biologic drugs for the treatment of inflammatory disease include:

- **Equity and excellence: liberating the NHS: Transparency in outcomes – a framework for the NHS**
- **Operating framework for the NHS in England 2012-13**
- **NHS outcomes framework 2012-13**
- **Procurement guide for commissioners of NHS funded services 2010.**
- **Innovation health and wealth: accelerating adoption and diffusion in the NHS**
- **Quality, innovation, productivity and prevention**
- **Commissioning for quality and innovation** makes a proportion of providers’ income conditional on quality and innovation
A stronger local voice: a framework for creating a stronger local voice in the development of health and social care services.

The National Audit Office: Services for people with rheumatoid arthritis

Although many or all of these priorities may be relevant to the services nationally, your local service redesign may address only one or two of them.

References

1. Royal College of Nursing (2009) Assessing, managing and monitoring biologic therapies or inflammatory arthritis: Guidance for rheumatology practitioners
12. The Kings Fund for the Rheumatology Futures Group (2009) Perceptions of patients and professionals on rheumatoid arthritis care
Specifying a service for people requiring biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology

Service components

The key factors in commissioning biologic drugs for the treatment of inflammatory disease are:

- ensuring all eligible patients have access to prompt and timely cost-effective treatment
- developing high-quality cost-effective services for the safe administration and monitoring of biologic drugs.

Ensuring all eligible patients have access to prompt and timely cost-effective treatment

Commissioners should work with clinicians and hospital trust managers to ensure that systems are in place that do not introduce unnecessary delays and that enable eligible patients to start biologic therapy in a timely fashion. This is crucial for achieving positive outcomes and limiting the progression of the disease[1][2].

Patients who are eligible for treatment with a biologic drug for inflammatory disease will usually be receiving care from specialist physicians or teams in secondary care, who are experienced in the diagnosis and management of disease in rheumatology, dermatology, gastroenterology or paediatric rheumatology. To ensure good coordination of care, particularly for patients with comorbidities, commissioners should work with clinicians across these specialities so that the appropriate pathways are in place.

To ensure clinical effectiveness and cost-effectiveness, the local eligibility criteria for access to treatment with biologic drugs for inflammatory disease should be in line with NICE recommendations. Clinicians and commissioners should consider how they can ensure that the eligibility criteria is correctly applied, adhered to and monitored. See an example of an authorisation process from NHS East Lancashire and NHS Blackburn with Darwen Care Trust Plus (Figure 2).

Figure 2: Prior approval for biologic drugs in NHS East Lancashire and NHS Blackburn with Darwen Care Trust Plus

NHS East Lancashire and NHS Blackburn with Darwen requires local clinicians who are prescribing biologic drugs to complete a ‘prior approval’ ‘tick box’ form that is submitted and checked by the hospital pharmacy before treatment is authorised. Additional ‘continuation’ forms which are completed following routine review, and also ‘discontinuation’ forms which instruct that treatment with a particular drug should be stopped, complete the process.
The ‘tick box’ form is used to demonstrate that patients are receiving appropriate treatment in line with NICE recommendations. It shows:

- which drug and treatment schedule has been prescribed
- whether patients meet eligibility criteria for the treatment of the condition, using a series of ‘yes’ or ‘no’ answers
- whether patients have been offered evidence-based information about their treatment.

If a patient is not eligible for treatment, their case may be considered using the PCT’s Individual Funding Request processes, which are used when there are exceptional clinical circumstances. The PCT’s aim is to move from a paper based system to an electronic transfer of information and authorisation over time.

For further information on these prescription approval forms please see this example on the NICE shared learning database.

This example is offered to share practice and NICE makes no judgment on the compliance of this service with its guidance.

Commissioners should be aware that patients starting biologic drugs for the treatment of inflammatory disease will typically:

- Have a condition for which conventional treatments and/or pharmacotherapy has failed, or they have contraindications to conventional treatments and/or pharmacotherapy. Commissioners may wish to ensure that clinicians have tried alternative treatments and/or methods of drug administration in these cases.

- Meet the disease severity assessment criteria, in line with NICE guidance. Commissioners may wish to ensure that the specialist team are consistent in measuring patient disease severity.

The topic-specific advisory group asks commissioners to note that they may occasionally receive a request to fund treatment for an exceptional patient – that is, a patient who may benefit from treatment with a biologic drug but who does not meet the NICE selection criteria. When developing local policies and procedures for prescribing biologic drugs for exceptional patients, such as individual funding requests, commissioners and clinicians should take into account the impact of the drug on the patient’s quality of life, the patient’s preferences and the perceived cost-effectiveness of the treatment.

Exceptional patients include but are not limited to:

- **Children**: NICE makes recommendations on biologic drugs for juvenile idiopathic arthritis (JIA) and Crohn’s disease. Commissioners should be
aware that there may be children with other active inflammatory diseases, such as psoriasis, who may benefit from treatment with a biologic drug.

- **Young adults**: NICE makes recommendations for the treatment of juvenile idiopathic arthritis in children and young people. However, commissioners should be aware that some young adults over the age of 17 may have active juvenile idiopathic arthritis.

- **Patients with co-morbidities**: commissioners should ensure that there is good coordination of care across all specialist areas including dermatology, rheumatology and gastroenterology because a patient’s inflammatory condition may increase their susceptibility to co-morbidities. The presence of co-morbid conditions may affect an individual patient’s response to biologic drugs. See figure 8 and figure 9 for examples of care coordination.

- **Patients for whom a first biologic drug fails**: NICE makes recommendations for patients who have an adverse affect to biologic drugs within the first 3–6 months for all conditions. NICE also makes recommendations for treatment with a second and third biologic drug for patients with rheumatoid arthritis. Commissioners and clinicians should refer to the relevant NICE guidance for details. In all other circumstances local commissioning decisions may be required.

Commissioners should ensure that clinicians provide patients with information that enables them to make an informed decision about starting treatment with, or rejecting, a biologic drug, based on their assessment of the risks and benefits of treatment and cessation. It is good practice to ensure that the patient’s consent for treatment is recorded.

Commissioners should work with clinicians to assess and favour, where appropriate and without jeopardising patient outcomes or efficacy, the prescription of the most cost-effective drug recommended by NICE for each condition. An assessment of the most cost-effective drug will include consideration of:

- **Differences in clinical outcomes** for each of the drugs and conditions. Commissioners and clinicians should refer to the relevant NICE guidance and the ‘useful sources of information section’ within this guide

- **Drug dose**

- **Costs associated with administering biologic drugs to patients** and monitoring the patient’s safety and response

- **Opportunities for patients to self-administer biologic drugs at home**. When delivered to a patient’s home by a home-care company, biologic drugs are exempt from VAT

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\[d\] Further information on assessment, management and resource planning for children can be found in the Royal College of Nursing’s guidance on assessing, managing and monitoring biologic therapies for inflammatory arthritis and from the British Society for Paediatric and Adolescent Rheumatology.
**Savings from patient access schemes.** Patient access schemes are provided by pharmaceutical companies to enable patients to gain access to selected high costs drugs. NICE recommends some biologic drugs for the treatment of inflammatory disease if there is a patient access scheme in place. Where patient access schemes provide cost savings in the first year of treatment, commissioners should be mindful that they will need to budget for the full cost of treatment in subsequent years.

**Developing high-quality cost-effective services for the safe administration and monitoring of biologic drugs**

When developing contracts and service specifications, commissioners should work alongside clinicians and hospital managers to develop robust and transparent quality and clinical governance arrangements for prescribing and delivering biologic drugs across different clinical specialities. Quality and clinical governance arrangements, along with clear selection criteria, could prevent the need for biologic drug prescriptions to be authorised on a case-by-case basis, thereby avoiding delays in initiating therapy and excessive administrative procedures. See the example from South Staffordshire PCT (Figure 3).

**Figure 3: Developing a biologic drugs commissioning policy in South Staffordshire PCT**

Faced with a 22% annual growth in the demand for, and expenditure on, biologic drugs, South Staffordshire PCT is developing a commissioning policy for biologic drugs for inflammatory disease.

The policy will be underpinned by NICE guidance and informed by clinicians and the latest available clinical evidence. The policy will:

- Ensure that, before starting treatment with biologic drugs, patients have tried alternative conventional therapies, that these therapies have failed to control symptoms, and that alternative administration methods have been attempted (for example trying subcutaneous methotrexate for patients who are intolerant to oral methotrexate).
- Agree the local process for initiating biologic therapy. Clinicians prescribe the drug: this prescription is then checked by pharmacists to ensure it aligns with NICE recommendations, the local commissioning policy and available budget.
- Detail a process for considering exceptional patients.
- Outline procedures for monitoring patient response in accordance with NICE recommendations.
- Detail procedures to be followed after the failure of treatment with a biologic drug.
- Specify rules for continuing and stopping biologic therapies after treatment failure.
Audit will be used to ensure that clinicians are complying with the policy and to address any issues that emerge.

*This example is offered to share practice and NICE makes no judgement on the compliance of this service with its guidance.*

Commissioners may wish to work with clinicians to develop comprehensive rules for the **continuation or maintenance** of a patient’s treatment with a biologic drug. These rules should comply with [NICE recommendations](#), and may include guidance for:

- monitoring patient response
- treatment after the failure of a first biologic drug
- criteria for the discontinuation of therapy and palliative care options.

Further information about the maintenance and discontinuation of treatment may be found in the [NHS clinical knowledge summary for biologic drugs](#).

Because biologic drugs are a relatively new treatment, their long-term efficacy and side-effects are not fully known. It is important that records are kept of all patients who are eligible for and receiving biologic drugs for the treatment of inflammatory disease. Records should include dates of consultations and drug administrations, and demonstrate that patients fulfil [NICE eligibility and continuation criteria](#). A current and accurate record can contribute to budget management, clinical governance, and audit and monitoring systems. See the example from Royal Derby NHS Trust (Figure 4). Commissioners should also encourage clinicians to use the national biologic drugs databases operated by the [British Society for Rheumatology](#), [British Association of Dermatology](#) and [British Society for Paediatric and Adolescent Rheumatology](#) (currently there is no register specific to gastroenterology).

### Figure 4: Royal Derby NHS Trust rheumatology biologics database

Nurse specialists use locally agreed algorithms to collect data on all patients before starting treatment with biologic drugs. Measurements include the patient’s disease activity scores, previous disease-modifying anti-rheumatic drug (DMARD) treatment, contraindications to treatment and smoking status. Once the patient starts therapy, data on patient response is collected at 3 months and then at 6-monthly check-ups.

This data is fed into a database, which holds data on all patients who are currently taking, or have previously taken, biologic drugs. The database is maintained by a database clerk whose salary is paid for by the local PCTs.

The database prevents the need for case-by-case approval of biologic drugs. It is used to:
- keep up-to-date **records** on patients who are prescribed and receiving biologic drugs
- monitor **compliance** with NICE eligibility and criteria
- provide regular **reports** to the host PCTs: this contributes to their **audit** and **budget** management processes
- allow more detailed **audits** to be performed at the request of the PCTs
- manage **pharmacovigilance**, risk and safety
- contribute to understanding the short- and long-term **effectiveness** of biologic drugs
- allow **research** projects to take place in the department.

*This example is offered to share practice and NICE makes no judgement on the compliance of this service with its guidance.*

There is a large and potentially increasing demand for biologic drugs, therefore it is important that commissioners manage their budget proactively to ensure that all eligible patients have access to the drugs in accordance with **NICE guidance**. Commissioners may wish to forecast the likely demand for biologic drugs for inflammatory disease in their area, and to set aside the funding required to meet this need. The NICE **forward planner**, **costing tools** and **commissioning and benchmarking tool** may assist with forecasting. See the example from Bristol Health Community (Figure 5).

**Figure 5: Meeting the demand for biologic drugs in the Bristol Health Community**

To ensure that funding is available for all eligible patients to access biologic drugs for inflammatory disease, the Technology Appraisals Implementation Team for three acute trusts and three primary care trusts in the Bristol area operate a proactive four stage system:

- The team use the NICE **forward planner** to identify upcoming NICE technology appraisals (TAs) and allocate a provisional budget to each prospective and published TA for the financial year.
- An **implementation plan** is prepared at the final appraisal determination (FAD) stage and finalised on publication of the final guidance. This estimates the number of eligible patients, immediate and long-term cost impact, and actions required for implementation. It also anticipates the impact on waiting lists, referral patterns and human resources. The group reviews the funding set aside to meet the estimated cost and compares this against the NICE costing tools.
- After implementation, monthly **monitoring** of actual uptake and expenditure is fed back to the PCT; figures are readjusted where they differ significantly from initial estimates.
- Periodic **audit** of practice is used to identify and resolve any issues.

*This example is offered to share practice and NICE makes no judgement on the compliance of this service with its guidance.*
Commissioners may wish to consider collaborating with sub-regional or regional partners when commissioning biologic drugs – for example, at regional medicines management or commissioning groups. There are several advantages to sub-regional or regional collaboration when commissioning biologic drugs, including:

- developing regional commissioning strategies to ensure all commissioners apply the same clinical thresholds and processes, to help reduce inequalities in patient access to drugs
- sharing good practice and resources such as audit criteria, audit pharmacists, or contracts for the home delivery of biologic drugs
- achieving economies of scale and improving quality and accountability by regional tendering or negotiating contracts for services, such as home delivery for biologic drugs
- negotiating with pharmaceutical companies to achieve reductions in the cost of drugs
- preventing duplication of resources in the development of policies, procurement strategies and contracts for biologic drugs.

**Service models**

Commissioners may wish to consider commissioning biologic drugs for the treatment of inflammatory disease in a number of different ways. These should be informed by the patient’s needs and preferences, and provide opportunities for care closer to home. Mixed models of provision may be appropriate across a local health economy.

Commissioners should ensure that a patient’s care pathway is led by a specialist multi-disciplinary team including specialist physicians and nurses. Typically the team will be based in a secondary care setting. However, commissioners may wish to consider the possibility of developing services provided by specialist teams in a community setting. See the example from Pennine Musculoskeletal Partnership Ltd (Figure 6). The team should always maintain a treatment plan, provide regular reviews of the patient’s response in accordance with NICE guidance and maintain responsibility for prescribing biologic drugs, including any that are delivered by third-parties.

**Figure 6: Community-based care for rheumatology patients in Oldham**

Pennine Musculoskeletal Partnership Ltd provides community-based care for all people with inflammatory arthritis and osteoarthritis in Oldham. The service is conveniently located in the town centre, and is provided by a rheumatology integrated care and assessment team (ICAT) that includes consultant rheumatologists, GPs with specialist interest, a nurse consultant, nurse specialists, occupational therapists, physiotherapists and podiatrists.
Care pathways are led by nurse specialists. Patients who are identified and assessed as eligible for biologic drugs in accordance with NICE guidance are referred to a consultant rheumatologist for the prescription. Ongoing patient response is measured by nurse specialists, who also coordinate and monitor the services provided by home-care companies.

Other services for patients taking biologic drugs include a telephone helpline providing advice and follow-up care for patients and an infusion clinic.

*This example is offered to share practice and NICE makes no judgement on the compliance of this service with its guidance.*

With support and training most patients can **self-administer** subcutaneous biologic drugs at home. Training may be provided by the specialist team or by a private home-care company. Patients should understand how to respond to unanticipated side-effects. See the example from the Aneurin Bevan Health Board (Figure 7). Commissioners should engage primary care colleagues to ensure that they identify, manage or refer patients with issues related to biologic drugs. Commissioners may also consider commissioning a **telecare or telehealth service** to provide telephone or online support for patients taking biologic drugs. This may help reduce the number of patients’ appointments and their travel time, and free-up clinics for priority patients.

**Figure 7: Care for patients with psoriasis in Aneurin Bevan Health Board**

The safety net for patients taking biologic drugs is provided by both primary and secondary care, with primary care dealing with minor issues and secondary care with more urgent issues. Patients receive training from clinical nurse specialists to help them understand what they should do if they have an unexpected problem with their health; patients are encouraged to involve secondary care early, to prevent minor problems from becoming exacerbated.

*This example is offered to share practice and NICE makes no judgement on the compliance of this service with its guidance.*

Most patients who self-administer biologic drugs, and some who receive infusions, will have their drugs delivered to their home by a private **home-care service**. When commissioning home-care services commissioners should:

- ensure that the home-care service is well integrated into the care pathways provided by the specialist multidisciplinary teams
- provide a quality assurance system to monitor the efficacy, safety and quality of the home-care service provided
- ensure that the home-care service is meeting the needs of patients
- negotiate with home-care services to ensure that they are receiving a cost-effective service
• consider whether similar services could be delivered in a more
cost-effective manner by other enterprises or by developing or
using their own home-care services.

Some patients may need to attend community or hospital facilities for the
infusion of intravenous drugs. Commissioners may wish to consider whether
they have sufficient day-case facilities to meet the demand for these patients,
and that they can provide this care close to a patient’s home where possible.
They may also wish to provide shared-infusion clinics across the range of
inflammatory conditions where biologic drugs may be used; see the examples
from the Royal Derby NHS Trust (Figure 8) and Leeds General Infirmary
(Figure 9).

**Figure 8: Combined joint and skin clinics for patients with psoriatic arthritis in Royal Derby NHS Trust**

The monthly combined joint and skin clinic is provided by rheumatology and
dermatology nurse specialists. The aim is to provide better coordinated care
for patients with psoriatic arthritis.

The clinic provides:
• individual patient response scores (PASI [psoriasis area severity index]
  and PsARC [psoriatic arthritis response criteria]) for dermatology and
  rheumatology
• annual skin cancer screening
• the opportunity for patients to discuss both joint and skin problems.

The clinic enables the coordination of treatment across dermatology and
rheumatology, including the use of an appropriate biologic drug for both
conditions, resulting in better skin and joint outcomes for the patient.

The trust also operates a combined day case unit where infusions for
rheumatology and dermatology are delivered.

This example is offered to share practice and NICE makes no judgement on
the compliance of this service with its guidance.

**Figure 9: Combined clinics for inflammatory diseases in Leeds General Infirmary**

Some patients who have one immune-mediated inflammatory disease (IMID)
may also have a second related IMID – for example, patients with Crohn’s
disease who also have ankylosing spondylitis or rheumatoid arthritis. To
improve the quality and coordination of patient care for such patients, the
gastroenterology and rheumatology departments run a bi-monthly joint clinic
to help ensure that their choice of biologic therapy is appropriate for both
conditions.
Leeds General Infirmary also operates a combined infusion clinic for IMIDs, operated by a specialist IMID nursing team. The team oversees biologic drug infusions and nurse specialists monitor patient response. Advantages to this model include specialist nurse review reducing out-patient follow up and drug vial sharing\(^*\) between patients, which greatly reduces cost.

*This example is offered to share practice and NICE makes no judgment on the compliance of this service with its guidance.*

**Service specification**

Local stakeholders, including clinicians and service users, should be involved in determining what is needed when commissioning biologic drugs for the treatment of inflammatory disease in order to meet local needs. The service should be patient-centred and integrated with other elements of care for people with inflammatory disease.

The service specification needs to consider:

- How quickly any changes in service provision are likely to take place
- Staff competencies, including possible training requirements. See Skills for Health [long term conditions case management competence framework](#)
- The number of patients with each condition who are prescribed biologic drugs, including estimates of future demand and numbers of patients who will cease therapy
- Service accessibility, with opportunities to provide care closer to home. This should take into account the age profile of the population, time, distance and cost of travel to secondary or primary care facilities (this may differ between rural and urban areas) and the needs of vulnerable patients
- Patient’s views on preferred methods and locations for administering biologic drugs and monitoring their outcomes. This might include their views on cost and time impact of alternative methods and how this affects their quality of life
- Rules for the identification of patients, initiation and continuation of therapy
- The patient care pathway

\(^*\) NICE has not considered or made recommendations relating to vial sharing. Where clinicians undertake vial sharing, clinical governance processes should take full account of licensing, safety and good manufacturing practice. For further information please consult the NPSA safety alert [Promoting Safer Use of Injectable Medicines](#). Standards for the preparation and manufacture of injectable medicines within hospital pharmacies are set out in [EL(97) 52 Aseptic Dispensing in NHS Hospitals](#) and the [European Union Guide on Good Manufacturing Practice](#).
Available resources, both financial and human

- Planned service improvement, including redesign, quality, equitable access, and referral-to-treatment times
- Address any safeguarding concerns and promote the welfare of children and vulnerable adults
- Service monitoring criteria.

Useful sources of information may include:

- British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR) rheumatoid arthritis guidelines on eligibility criteria for the first biological therapy.
- European Crohn’s and Colitis Organisation’s consensus on the management of Crohn’s disease and ulcerative colitis.
- The standard NHS contracts for acute hospital, mental health, community and ambulance services.
- NHS Evidence: provides free access to clinical and non-clinical information – local, regional, national and international.
- NHS networks: learning from practice database offers examples of innovative commissioning across the NHS and its partners.
- The NICE shared learning database offers examples of how organisations have implemented NICE guidance locally.

References


Determining local service levels for biologic drugs for the treatment of inflammatory disease

Benchmarks for a standard population

Available data suggest that the indicative benchmark for adults aged 18 years or older needing biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology is 0.19% or 190 per 100,000 adult population per year.

For a standard population of 100,000, around 80% or 80,000 people would be aged 18 or older. The average number of people needing biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology is around 150 per year (which equates to 0.19% of the population aged 18 years or older).

For an average practice with a list size of 10,000, around 80% or 8,000 people would be aged 18 years or older. The average number of people with inflammatory disease in rheumatology, dermatology and gastroenterology needing biologic drugs is 15 per year (which equates to 0.19% of the population aged 18 years or older).

Owing to the small number of children who may be eligible for biologic drugs, separate benchmarks for juvenile idiopathic arthritis and children with Crohn’s disease are provided later in the guide.

Examine the assumptions used in estimating these figures.

Commissioning biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology is likely to fall under the programme budgeting categories 213X (problems of the gastrointestinal system), 214X (problems of the skin) and 215X (problems of the musculoskeletal system).

Use the biologic drugs commissioning and benchmarking tool to determine the level of service that might be needed locally and to calculate the cost of commissioning the service using the indicative benchmark and/or your own local data. The commissioning and benchmarking tool contains a sensitivity analysis for each condition which provides a range to reflect the uncertainties within published literature, audit and clinical opinion on the rapidly changing uptake of biologic drugs for inflammatory disease.

Further information

Sources of further information to help you in assessing local health needs and reducing health inequalities include:
Annex A of the Commissioning framework for health and well-being outlines the process and data needed to undertake a joint strategic needs assessment.

Department of Health Delivering quality and value – focus on benchmarking.

NICE Health equity audit – learning from practice briefing.

NHS Comparators provides comparator data for NHS commissioning and provider organisations to enable users to investigate aspects of local activity, costs and outcomes.

The Disease management information toolkit (DMIT) is a good-practice tool for decision-makers, commissioners and deliverers of care for people with long-term conditions, which presents data on conditions that contribute to high numbers of emergency bed days. It models the effects of possible interventions that may be commissioned at a local level and helps users to consider the likely impact of commissioning options.

PARR (Patients at risk of rehospitalisation) is a risk prediction system for use by primary care trusts to identify patients at high risk of hospital re-admission.

PRIMIS+ provides support to general practices on information management, recording for, and analysis of, data quality, plus a comparative analysis service focused on key clinical topics.
Assumptions used in estimating a population benchmark

Several assumptions have been used to estimate the population benchmark for adults requiring biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology, of 0.19% or 190 per 100,000 adult population per year. These assumptions are based on the following information sources:

- **epidemiological data** on the number of people with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn’s disease and ulcerative colitis. The benchmark was developed using the expert clinical opinion of the topic-specific advisory group, based on experience in clinical practice, audit and published literature.

- **activity data** procedure codes associated with high cost drugs.

For the purpose of this commissioning guide the adult population aged 18 years or older in England has been used except where specified.

**Epidemiological data**

This commissioning guide focuses on the use of biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology.

The conditions included in the population benchmark are adults needing biologic drugs for the treatment of the following inflammatory conditions: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn’s disease and ulcerative colitis. It has been assumed that the number of patients discontinuing treatment each year is approximately equal to the numbers of new patients starting treatment, unless otherwise stated.

Commissioners should take into account local circumstances to determine the number of patients eligible for and receiving biologic drugs for the treatment of inflammatory disease. A sensitivity analysis for the number of patients receiving biologic drugs is available in the commissioning and benchmarking tool.

**People aged 18 years and older**

**Rheumatoid arthritis**

Rheumatoid arthritis is a chronic long-term inflammatory disease. The use of biologic drugs for treating rheumatoid arthritis has been increasing in recent years and is now levelling off in some areas.

The prevalence of rheumatoid arthritis in England is 0.86%[1] of the adult population or around 350,000 people. It is estimated that around 10%[2] of
people with rheumatoid arthritis will be eligible for and receiving biologic drugs. This equates to around 35,000 people in England.

Available data suggests that the indicative benchmark rate for the number of people with rheumatoid arthritis eligible for and receiving treatment with biologic drugs is 0.086%, or 86 per 100,000 adults aged 18 years or older per year.

**Ankylosing spondylitis**

Ankylosing spondylitis is a disease that causes inflammation mainly in the lower spine, which results in back pain and stiffness. It affects around 70,000 people in England[^3], and around 20,000 of these will be eligible for treatment with biologic drugs[^2].

Expert clinical opinion suggests that biologic drugs may not be the most appropriate treatment for all eligible patients. According to expert clinical opinion 30%[^2], or around 6,800 of the 20,000 eligible patients will take up treatment.

Available data suggests that the indicative benchmark rate for the number of people with ankylosing spondylitis receiving treatment with biologic drugs is 0.017%, or 17 per 100,000 adults aged 18 years or older per year.

**Psoriatic arthritis**

Psoriatic arthritis is a unique inflammatory arthritis associated with psoriasis[^4]. Because of the problems in definitively diagnosing psoriatic arthritis, there are few studies on the incidence and prevalence of the disease. The results vary widely depending on the cohort studied and the diagnostic criteria used, ranging from 0.3% to 1%[^5] of the population. This is examined further in the commissioning and benchmarking tool.

For the purpose of this benchmark a midpoint of prevalence of 0.65% has been used. This equates to around 260,000 adults in England with psoriatic arthritis. The proportion of prevalent patients receiving treatment with a biologic drug is estimated to be around 2.4%[^6] or around 6,200 people.

Available data suggest that the indicative benchmark rate for the number of people with psoriatic arthritis eligible for and receiving treatment with biologic drugs is 0.016% or 16 per 100,000 adults aged 18 years or older per year.

**Plaque psoriasis**

Plaque psoriasis is common in the population and effects around 600,000 or 1.5%[^4] of adults in England.

There is debate around the proportion of these patients who are eligible for and receiving treatment with a biologic drug, ranging from 1.1% to 5%[^2][^7][^8]. This is examined further in the commissioning and benchmarking tool. It should be noted that expert clinical opinion suggests that, because of the
nature of the condition, not all patients eligible for biologic treatments will currently be identified and treated with them.

For this benchmark the proportion of prevalent patients eligible for treatment with a biologic drug is estimated to be around 3%\textsuperscript{[2]} or 18,000 people. A small proportion of patients will also have psoriatic arthritis and be eligible for treatment for both their psoriasis and psoriatic arthritis.

Available data suggest that the indicative benchmark rate for the number of people with psoriasis eligible for and receiving treatment with biologic drugs is 0.045%, or 45 per 100,000 adults aged 18 years or older per year.

**Crohn's disease**

Crohn's disease is a chronic inflammatory condition affecting the gastrointestinal tract. People with Crohn's disease have acute exacerbations of the symptoms in between periods of remission or less active disease. Around 80,000\textsuperscript{[9]} adults in England have Crohn's disease.

It is estimated that a total of around 13% or 10,500\textsuperscript{[2][9]} adults will have severe active Crohn’s disease or fistulising Crohn's disease and be eligible for treatment with biologic drugs. These are patients who are either intolerant to conventional therapy or for whom conventional therapy has failed. Available data suggest that the indicative benchmark rate for the number of people with Crohn’s disease eligible for and receiving treatment with biologic drugs is 0.026%, or 26 per 100,000 adults aged 18 years or older per year.

**Ulcerative colitis**

Ulcerative colitis is a form of colitis, a disease of the large intestine or colon. Ulcerative colitis is an intermittent disease, with periods of exacerbated symptoms, and periods that are relatively symptom-free.

There are approximately 76,000\textsuperscript{[10]} people in England with ulcerative colitis. Of these, an estimated 6%\textsuperscript{[2]} (5000) have an acute exacerbation of severely active ulcerative colitis per year. It is estimated that 15%\textsuperscript{[2]} (750) of these patients would receive treatment with a biologic drug.

Available data suggest that the indicative benchmark rate for the number of people with ulcerative colitis receiving treatment with biologic drugs is 0.001%, or 1 per 100,000 adults aged 18 years or older per year.

**People under 18 years of age**

**Juvenile idiopathic arthritis**

Juvenile idiopathic arthritis (JIA) is a relatively rare disease, with an estimated incidence in the UK of 0.1 per 1000 children, equivalent to 1000 new cases per year. The prevalence is in the order of 1 per 1000 children, so about 8,500 children in England are affected\textsuperscript{[13]}. This equates to around 1,200 children who are eligible for and receiving treatment with biologic drugs\textsuperscript{[11]}. 


Children have been defined here as aged between 4 and 17 years. This benchmark does not include the small number of people aged 18 or older with long-standing JIA who are receiving treatment with biologic drugs.

Available data suggest that the indicative benchmark rate for the number of children aged 4–17 years with JIA eligible for and receiving treatment with biologic drugs is 0.015%, or 15 per 100,000 children per year.

**Crohn’s disease**

Around 1,800 children aged between 6 and 17 years in England have Crohn’s disease.

Using the methodology applied above for adult Crohn’s disease, it is estimated that a total of around 13% or 240 children will have severe active Crohn’s disease or fistulising Crohn's disease and be eligible for biologic drugs. These are patients who are either intolerant to conventional therapy or for whom conventional therapy has failed.

Available data suggest that the indicative benchmark rate for the number of children with Crohn’s disease eligible for and receiving treatment with biologic drugs is 0.003%, or 3 per 100,000 children, per year.

**Activity data**

Biologic drugs are often administered to patients with a moderate or severe form of a long-term inflammatory condition, who may be at high risk of hospital admission because of exacerbations of the disease. Commissioners may wish to track patients who are currently receiving high cost drugs, such as biologics, to show the level of activity in secondary care. This may be compared with activity without the use of high cost drugs such as biologics. The commissioning and benchmarking tool contains a data specification for the conditions mentioned in this guide and the OPCS4 procedure codes associated with high cost drugs.

**Conclusions**

Based on the epidemiological data and other information outlined above, it is concluded that the population benchmark for adults aged 18 years or older requiring biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology is 0.19%, or 190 per 100,000 adult population, per year.

In addition, 0.015%[9], or 15 per 100,000, children aged 4–17 years will also be eligible and receiving biologic drugs for the treatment of JIA. A further 0.003%, or 3 per 100,000, children aged 6–17 years will be eligible and receiving biologic drugs for the treatment of Crohn’s disease.
This is based on the following assumptions in the table below.

### Assumptions used in estimating the population benchmark for adults requiring biologic drugs for the treatment of inflammatory disease

<table>
<thead>
<tr>
<th>Condition</th>
<th>Estimated number of people with the condition</th>
<th>Estimated number of people with the condition eligible and receiving treatment with biologic drugs</th>
<th>Estimated percentage of people with the condition eligible and receiving treatment with biologic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid arthritis</td>
<td>350,000</td>
<td>35,000</td>
<td>10.0%</td>
</tr>
<tr>
<td>Ankylosing spondylitis</td>
<td>71,000</td>
<td>6,900</td>
<td>9.7%</td>
</tr>
<tr>
<td>Psoriatic arthritis</td>
<td>263,000</td>
<td>6,300</td>
<td>2.4%</td>
</tr>
<tr>
<td>Psoriasis</td>
<td>607,000</td>
<td>18,000</td>
<td>3.0%</td>
</tr>
<tr>
<td>Crohn's disease (adults)</td>
<td>81,000</td>
<td>10,500</td>
<td>13.0%</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>77,000</td>
<td>750</td>
<td>1.0%</td>
</tr>
<tr>
<td>Juvenile idiopathic arthritis</td>
<td>8,500</td>
<td>1,300</td>
<td>15.0%</td>
</tr>
<tr>
<td>Crohn's disease (children)</td>
<td>1,800</td>
<td>240</td>
<td>13.0%</td>
</tr>
</tbody>
</table>

Use the Determining local service levels for biologic drugs for the treatment of inflammatory disease [commissioning and benchmarking tool](#) to determine the level of service that might be needed locally and to calculate the cost of commissioning the service using the indicative benchmark and/or your own local data.

### References


2. Sensitivity analysis, in [commissioning and benchmarking tool](#)


The commissioning and benchmarking tool

Download the biologic drugs commissioning and benchmarking tool. Use the biologic drugs commissioning and benchmarking tool to determine the level of service that might be needed locally and to calculate the cost of commissioning the service, as described below.

**Identify indicative local service requirements**

The indicative benchmark based on the national average for the number of people with inflammatory disease in rheumatology, dermatology and gastroenterology is 0.19% or 190 per 100,000 population aged 18 years and older per year.

In addition, 0.015% or 15 per 100,000 children aged 4–17 years are eligible for and receiving biologic drugs for the treatment of juvenile idiopathic arthritis, per year and 0.003% or 3 per 100,000 children aged 6–17 years are eligible for and receiving biologic drugs for the treatment of Crohn’s disease, per year.

The commissioning and benchmarking tool helps you to assess local service requirements using the indicative benchmark rates as a starting point. With knowledge of your local population and its demographic, you can amend the benchmark to better reflect your local circumstances. For example, if your population is significantly younger or older than the average population or has a significantly higher or lower rate of inflammatory disease, you may need to provide biologic drugs for relatively fewer or greater numbers of people.

**Review current commissioned activity**

You may already commission biologic drugs for the treatment of inflammatory disease in rheumatology, dermatology and gastroenterology for your population. The tool provides tables that you can populate to help you calculate your current commissioned activity and costs.

You may wish to track patients who are currently receiving biologic drugs, to show the level of activity in secondary care. This may be compared to activity without the use of biologic drugs. The commissioning and benchmarking tool contains a data specification for the conditions mentioned in this guide and the OPCS-4 procedure codes associated with high cost drugs to enable you to do this.
**Identify future change in capacity required**

Using the indicative benchmark rates provided, or your own local benchmarks, you can use the commissioning and benchmarking tool to compare the activity that you may need to commission against your current commissioned activity. This will help you to identify the future change in capacity required. Depending on your assessment, your future provision may need to be increased or decreased.

**Model future commissioning intentions and associated costs**

You can use the commissioning and benchmarking tool to calculate the capacity and resources needed to move towards the benchmark level, and to model the required changes over a period of 4 years.

Use the tool to calculate the level and cost of activity you intend to commission and to consider the settings in which biologic drugs may be provided, comparing the costs of commissioning the service across the various settings. The tool is pre-populated with data on the potential recurrent cost elements that may need to be considered in future service planning, which can be reviewed and amended to better reflect your local circumstances.

The tool should be used to calculate the approximate cost of commissioning biologic drugs for your local population. Each of the biologic drugs approved by NICE for treatment of each condition, at the time of publication of this commissioning guide in December 2010 has been listed, with an estimated unit cost. The most appropriate or cost effective drug for each patient is not necessarily the drug with the lowest unit cost. Please refer to the original NICE guidance and associated costing tools for further details.

Commissioning decisions should consider both the clinical and economic viability of the service, and take into account the views of local people. Commissioning plans should also take into account the costs of monitoring the quality of the services commissioned.
Ensuring corporate and quality assurance

Commissioners should ensure that the services they commission represent value for money and offer the best possible outcomes for patients. Commissioners need to set clear specifications for monitoring and assuring quality and productivity in the service contract.

Commissioners should ensure that they consider both the clinical and economic viability of the service, and any related services, and take into account patients’ and carers’ views, and those of other stakeholders, when making commissioning decisions.

Commissioning biologic drugs for the treatment of inflammatory disease needs to:

- be effective and efficient
- be responsive to the needs of patients and carers
- provide treatment and care based on best practice, as defined in relevant NICE guidance
- deliver the required capacity
- be integrated with other elements of care for people needing biologic drugs, for example physiotherapy or occupational therapy services
- define agreed criteria for access, local protocols and the care pathway for people needing biologic drugs
- be patient-centred and provide equitable access, ensuring that patients are treated with dignity and respect, are fully informed about their care and are able to make decisions about their care in partnership with healthcare professionals
- consider and respond to recommendations arising from any audit, or serious untoward or patient safety incidents
- demonstrate how it meets requirements under national equalities legislation
- demonstrate value for money.

Local quality assurance

Any mechanisms for quality assurance at a local level are likely to refer to the following:

- Service and performance targets, including estimated activity levels and case mix, waiting and referral-to-treatment times (ensuring that patients and carers do not experience unnecessary delays), outcomes measures, complaints procedures.
• **Clinical governance arrangements**, including incident reporting and continuation rules.

• **Clinical quality criteria**, appropriateness of referral, consenting procedures, clinical protocols.

• **Audit arrangements**: commissioners may wish to consider the local or regional identification of a clinical audit lead for biologic drugs. A robust system will assist in monitoring the uptake and delivery of biologic drugs and may highlight issues such as inappropriate prescribing, and enable these to be mitigated and prevented in the future. NICE produces a number of clinical [audit tools](#) for biologic drugs, which can be further adapted to meet local circumstances.

• **Recording all patients receiving biologic drugs** using the appropriate database or register.

• **Pharmacovigilance** to ensure detection and reporting of any adverse side effects of biologic drugs in the short or long term.

• **Health, safety and security**: infection prevention, waste management, confidentiality procedures, legislative requirements, risk management.

• **Patient and service user experience** using the national patient survey; taking into account perspectives and perception of service provision to help shape services; engagement to inform commissioning decisions; complaints.

• **Patient outcomes** using appropriate and validated [patient reported outcomes](#) (PROMs).

• **Staff competencies**: individual and team baseline requirements, monitoring and performance, continuing professional development (CPD) for nurse specialists.

• **Information requirements**, including both patient-specific information (NHS number, provision of high-quality information to patients/carers) and service-specific information (referral-to-treatment times, workload trends, number of complaints).

• **The process for reviewing the service with stakeholders**, including decisions on changes necessary to improve the service.

• **Achieving targets associated with national equalities legislation**.

**Further information**

**General information** on quality and corporate assurance can be obtained from the following sources:

• [NHS Alliance online resources](#). NHS Alliance is the representational organisation of primary care and primary care
trusts, and provides them with an opportunity to network and exchange best practice. The alliance supports its members with an open-access helpline, in-house and joint publications and briefings, internal newsletters and a website.

- The DH commissioning framework provides guidance on the commissioning process in the context of the NHS reform agenda.

- NHS Institute for Innovation and Improvement support for commissioners, includes Commissioning for Health Improvement products to accelerate the achievement of world class commissioning; The Productive Leader programme to enable leadership teams to reduce waste and variation in personal work processes, and Better care, better value indicators to help inform planning, to inform views on the scale of potential efficiency savings in different aspects of care, and to generate ideas on how to achieve these savings.

- 10 Steps to your SES: a guide to developing a single equality scheme. This guidance has been developed to assist NHS organisations that have a duty, as public authorities, to comply with the race, disability and gender public sector duties, and in anticipation of new duties in relation to age, religion and belief, and sexual orientation.

**Specific information** on quality and corporate assurance for commissioning biologic drugs for the treatment of inflammatory disease can be obtained from the following sources:

- The British Association of Dermatologists biologic interventions register (BADBIR), British Society for Rheumatology biologics register (BSRBR) and British Society for Paediatric and Adolescent Rheumatology (BSPAR) register the number and outcomes of patients taking biologic drugs in dermatology and rheumatology

- The Inflammatory Bowel Disease Standards Group: Quality care: service standards for the healthcare of people who have inflammatory bowel disease

- Skills for health works with employers and other stakeholders to ensure that those working in the sector are equipped with the right skills to support the development and delivery of healthcare services. See details of the long-term conditions case management competence framework.
Service-specific Advisory Group: biologic drugs

A service-specific advisory group was established to review and advise on the content of the commissioning guide. This group met once, with additional interaction taking place via email.

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