SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	04/MSKT/0023
Service	Rheumatoid Arthritis and Cytokine/Biologic Drug Regimes Services
Commissioner Lead	MSK CCP
Provider Lead	Rheumatology Services – Acute Hospitals / Secondary Care
Period	1 April 2014
Date of Review	TBA

1. Population Needs

1.1 National/local context and evidence base

In the past ten years, biologic drugs have emerged as an important advance in the treatment of inflammatory disease such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease and ulcerative colitis.

These are chronic conditions which can cause pain, debilitation, loss of independence and premature mortality. These conditions may have a detrimental impact on a person's quality of life and place a significant financial burden on society.

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 people 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.

Where conventional treatments become ineffective, biologic drugs may slow the destruction of joints, reduce inflammation, slow disease progression or induce full remission.

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. Biologic drugs contain monoclonal antibodies and soluble receptors that specifically modify the disease process, by blocking key protein messenger molecules.

The drugs may also be referred to as biological drugs, biologic therapies, biologic interventions, or cytokine modulators.

Benefits

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

- reducing local and regional inequalities;
- improving clinical outcomes and the quality of life for people with inflammatory disease;
- ensuring that the drugs are prescribed and delivered in a safe environment by trained

and competent staff;
- improving systems for prescribing and administering biologic drugs to patients across rheumatology;
- 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;
- 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.

National drivers

National priorities and initiatives relevant to commissioning biologic drugs for the treatment of inflammatory disease include:
- Operating framework for the NHS in England 2014/15;
- NHS outcomes framework 2014/15;
- Innovation health and wealth: accelerating adoption and diffusion in the NHS;
- Quality, innovation, productivity and prevention;
- The National Audit Office: Services for people with rheumatoid arthritis;
- NICE Guidance.

Local Context and Background

In 2013, Rheumatology colleagues held meetings to discuss the development of local pathways for the use of biologics in psoriatic arthritis and ankylosing spondylitis and an update of the established local pathway for the use of biologics in rheumatoid arthritis.

The MSK CCP and CCG CCC agreed the new pathways for inclusion in 2013.
This specification confirms the agreed pathways that the CCG have agreed to commission for:

- Rheumatoid Arthritis
- Spondyloarthritis including Ankylosing Spondylitis
- Psoriatic Arthritis

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	*
Domain 2	Enhancing quality of life for people with long-term conditions	*
Domain 3	Helping people to recover from episodes of ill-health or following injury	
Domain 4	Ensuring people have a positive experience of care	*
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	

2.2 Local defined outcomes

Refer to local pathways

3. Scope

3.1 Aims and objectives of service

NICE guidance should be followed routinely in providing biologic drugs for the treatment of inflammatory disease. The attached CCG pathways for RA, AS and PA are outside current NICE guidance and should be adhered to in prescribing biologics for all Dorset patients.

Evidence will need to be collated that demonstrates the following:

- the best possible outcomes for individual patients and their carers
- all eligible patients are identified promptly and prescribed biologic drugs in accordance with the relevant NICE technology appraisal(s) and the CCG agreed pathways outside of NICE
- provide transparent and equitable care to everyone needing biologic drugs
- identify exceptional patients and ensuring that systems are in place that allow them to be considered for treatment with biologic drugs
- manage 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
- ensure 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.

3.2 Service description/care pathway

See attached / embedded pathways


MSK CCP RA pathway Aug 2014 FINAL.pdf


Biologics Pathway for Ankylosing Spondylitis


Biologics Pathway for psoriatic arthritis in Dc

3.3 Any acceptance and exclusion criteria and thresholds

The agreed pathways allow flexibility locally whilst still adhering to NICE guidelines and are for patients registered with a Dorset GP.

3.5 Interdependence with other services/providers

CCG Medicines Management Team
Individual Patient Treatment Team
Other Secondary Care Providers
Orthopaedics

4. Applicable Service Standards

4.1 Applicable national standards

This service specification should be read in conjunction with:

NICE clinical guideline CG79. Rheumatoid arthritis: the management of rheumatoid arthritis in adults

NICE technology appraisals:
TA130: Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis
TA143: Adalimumab, etanercept and infliximab for ankylosing spondylitis
TA186: Certolizumab pegol for the treatment of rheumatoid arthritis
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
TA 247: Tocilizumab for the treatment of rheumatoid arthritis
TA280: Abatacept (second line) for the treatment of rheumatoid arthritis (rapid review of TA234)

NICE algorithms as detailed below:
Rheumatoid arthritis commissioning algorithm
Ankylosing spondylitis commissioning algorithm
Psoriatic arthritis commissioning algorithm
Quality Standard 33 Rheumatoid Arthritis

Current list as at March 2014, NICE website should be checked for any subsequent guidance.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)
Not applicable

4.3 Applicable local standards
Local reporting requirements Cytokine Notification and Review Form

Cytokine Notification FOR RA - AS - PA FIN

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)
Not applicable

5.2 Applicable CQUIN goals (See Schedule 4 Part E)
Not applicable

6. Location of Provider Premises

Provided as part of the Rheumatology Services delivered by the acute trusts to patients registered with a Dorset GP

7. Individual Service User Placement

Not applicable