**Humber and North Yorkshire Integrated Care Partnership**

**Area Prescribing Committee**

**Traffic Light – Red Amber Green 'RAG' Status**

**Formulary Definitions**

**Contents**

[What is a Local Formulary? 2](#_Toc194594969)

[Key Features of a Local Formulary: 2](#_Toc194594970)

[Benefits of a Local Formulary: 3](#_Toc194594971)

[Who Develops and Maintains the Local Formulary? 3](#_Toc194594972)

[Traffic Light – Red Amber Green – 'RAG' Status - Summary Table 1](#_Toc194594973)

[What do we mean by a 'specialist\*'? 1](#_Toc194594974)

[Accepting Shared Care from 1](#_Toc194594975)

[a) Outside the ICB geography and/or 1](#_Toc194594976)

[b) Private Providers 1](#_Toc194594977)

[What do we mean by 'primary care'? 2](#_Toc194594978)

[Full Rationale/Definitions of Traffic Light – Red Amber Green – 'RAG' Status 2](#_Toc194594979)

[Red Drugs 2](#_Toc194594980)

[Key Characteristics of Red Drugs: 2](#_Toc194594981)

[Responsibilities for red drugs: 3](#_Toc194594982)

[Challenges of Red Drug Classification: 4](#_Toc194594983)

[Amber Shared Care Protocol (Amber SCP) 4](#_Toc194594984)

[Key Characteristics of Amber Shared Care Drugs: 4](#_Toc194594985)

[Benefits of Shared Care: 5](#_Toc194594986)

[Challenges of Shared Care: 5](#_Toc194594987)

[Amber Specialist Initiation (Amber SI) 6](#_Toc194594988)

[Benefits of Amber Specialist Initiation Drugs: 7](#_Toc194594989)

[Responsibilities of Amber Specialist Initiation Drugs: 7](#_Toc194594990)

[Amber Specialist Recommendation – Amber SR 8](#_Toc194594991)

[Key Features of Amber Specialist Recommendation Drugs: 8](#_Toc194594992)

[Benefits of the Amber Specialist Recommendation System: 9](#_Toc194594993)

[Responsibilities of the Amber Specialist Recommendation System: 9](#_Toc194594994)

[Green Drugs 10](#_Toc194594995)

[Key Characteristics of Green Drugs: 10](#_Toc194594996)

[Responsibilities when prescribing green drugs: 11](#_Toc194594997)

[Benefits of Green Drug Classification: 11](#_Toc194594998)

[Other definitions 12](#_Toc194594999)

[HNY Medicines Related Shared Care and/or the Administration of Medicines Locally Enhanced Service 12](#_Toc194595000)

## **What is a Local Formulary?**

A **local formulary** is a document or resource developed and maintained by healthcare organisations to provide guidance on the prescribing of medicines within a specific geographical area or healthcare setting. It acts as a reference for clinicians to ensure safe, effective, and cost-efficient use of medicines that are appropriate for the local population's needs.

Our local formulary is decided by the [Humber and North Yorkshire Area Prescribing Committee,](https://humberandnorthyorkshire.org.uk/area-prescribing-committee-apc/) and the formulary is hosted <here>.

**Currently hosted:**

Former Humber APC - <https://www.apcnlgformulary.nhs.uk/about.asp>

Former North Yorkshire and York APC –

<https://www.northyorkshireandyorkformulary.nhs.uk/default.asp?siteType=Full>

It will move to the new HNY online platform when ready.

### **Key Features of a Local Formulary:**

* **List of Approved Medicines**:

Includes a comprehensive list of medications approved for prescribing for named/specific indications within the local area.

* **Prescribing Guidance**:

Provides recommendations on the first-line, second-line, and specialist-only medicines.

Details the circumstances under which specific drugs should be used (e.g., based on patient conditions or specific criteria).

* **Traffic Light System (or RAG status):**

**See below.**

* **Evidence-Based Recommendations**:

Local formularies should be developed using national guidelines such as those from the **National Institute for Health and Care Excellence (NICE)**, [NICE guidance on formularies](https://www.nice.org.uk/guidance/mpg1) – and local clinical expertise.

* **Special Considerations**:

The formulary should include guidance for special populations, such as paediatric, elderly, or pregnant patients.

Addresses specific regional healthcare needs or challenges.

### **Benefits of a Local Formulary:**

* **Promotes Consistency**: Ensures uniform prescribing practices across the region.
* **Improves Safety**: Reduces inappropriate prescribing and minimises medication-related errors.
* **Cost-Effectiveness**: Encourages the use of the most cost-effective medicines.
* **Supports Clinicians**: Acts as a decision-support tool for healthcare professionals.
* **Optimises Patient Outcomes**: Encourages the use of evidence-based treatments tailored to the local population.

### **Who Develops and Maintains the Local Formulary?**

The Humber and North Yorkshire Formulary is maintained and updated by the [Humber and North Yorkshire Area Prescribing Committee (APC)](https://humberandnorthyorkshire.org.uk/area-prescribing-committee-apc/).

The APC includes pharmacists, doctors, and other healthcare professionals who review and update the formulary regularly based on new evidence, NICE guidelines, and local healthcare priorities.

The local published formulary should include:

* Name of the drug/device
* Strength/formulation
* Traffic light 'RAG' status – see below.
* Specific indications associated with the RAG status
* Any local guidance/protocols etc.

## **Traffic Light – Red Amber Green – 'RAG' Status - Summary Table**

|  |  |  |
| --- | --- | --- |
| **Colour/name** | **Formulary annotation/key** | **Description** |
| **Red** | **R** | **Specialist use only.** The specialist\* initiates AND continues all prescribing and completes all ongoing monitoring. |
| **Purple** | No longer used – now 'Red' – see above | **See 'red' above** |
| **Amber Shared Care Protocol (Amber SCP)** | **A SCP**The formulary entry should also link to the local SCP. | **Specialist initiation and requires ongoing monitoring.**Medicines that must be initiated and stabilised by a specialist\*. This includes dose titration by the specialist, up to a stable and effective dose. They are suitable to be prescribed in primary care once the patient is on a stable dose, but they require significant monitoring on an ongoing basis. Routinely the ongoing monitoring will be completed by primary care as part of an agreed service.The patient remains under the care of both the specialist and the primary care team. The patient cannot be 'discharged' from the specialist's care under shared care arrangements.There will be a shared care protocol (SCP) for the specific drug. The specialist and the primary care prescriber must follow the approved shared care protocol in place.Full agreement to share the care of each specific patient must be reached under the shared care protocol (SCP) which must be provided to the primary care provider.If a commissioned SCP is not available these must be treated as red. If a commissioned SCP is out of date, it may be treated as a red drug. |
| **Amber Specialist Initiation** **(Amber SI)** **Formerly known as Amber 2 in Humber** | **A SI** | Must be started by a specialist\* and remain with the specialist until the patient is stable on the new medicine. It can then be transferred to primary care to continue prescribing without ongoing arrangements between the specialist and primary care. Primary care can refer back to a specialist at any time in relation to medication queries, if required. |
| **Amber specialist recommendation (Amber SR)**Formerly known as Amber 1 in Humber | **A SR** | Does not need to be initiated by a specialist but can be recommended by a specialist to primary care.No ongoing arrangements between specialists and primary care. Primary care can refer back to a specialist at any time in relation to medication query if required. |
| **Green with guideline (with LOCAL pathway/guideline/protocol)**Formerly known as Amber 1 in Humber | **GG**The formulary entry should also link to the local pathway/guidance. | Can be prescribed in primary care and by specialists in line with a recommended approved LOCAL pathway/guideline. Local = written and approved within Humber and North Yorkshire ICS.The formulary entry should link to the local pathway/guidance. (Please note - All medicines include some form of guidance, even if that is just the BNF. Green with guideline refers to the publication of approved local guidelines/pathways/protocols, etc.) |
| **Green** (no pathway/guideline) | **G** | Medicines suitable for routine use within primary care and secondary care.It can be prescribed in primary care, as per the wording on the formulary and considering both the drug SPC and BNF. |
| **Deny List – not routinely commissioned (NRC)**  | **NRC** | Not routinely commissioned. These drugs have been formally considered by the APC and are not recommended for prescribing due to, e.g. safety/cost. |

## **What do we mean by a 'specialist\*'?**

* In terms of the formulary traffic light status, a 'specialist' is typically any prescribing healthcare professional/ clinician with advanced expertise in a particular medical field. Their role involves diagnosing conditions, initiating specific treatments, and managing complex aspects of patient care.
* A specialist may be a doctor, a dentist or another registered healthcare professional with a non-medical prescribing qualification, for example, a nurse or pharmacist.
* The specialist service may be hosted by the NHS, for example, acute trusts, mental health providers, and community providers OR it may be a private provider. This category also includes medicines not commissioned by the Integrated Care Board, for example, medicines commissioned by the Local Authority.
* We acknowledge that GMC defines 'specialist' in terms of the GMC ['Specialist Register',](https://www.gmc-uk.org/registration-and-licensing/our-registers/a-guide-to-our-registers/specialist-registration) and there is current debate regarding General Practitioners being recognised as specialists.
* Within the definitions for RAG status and shared care, a specialist is a particular medical condition/umbrella of conditions passing care to another healthcare professional in a primary care setting. The healthcare professional in primary care may also be a specialist but it is not a requirement of RAG/shared care.

## **Accepting Shared Care from**

## **a) Outside the ICB geography and/or**

## **b) Private Providers**

* Humber and North Yorkshire ICB borders five other ICB geographies: West Yorkshire ICB, South Yorkshire ICB, North East and North Cumbria ICB, Lincolnshire ICB and Nottingham and Nottinghamshire ICB. Our patients are seen by providers outside our ICB area, both via the NHS and via private routes.
* Overall, NHS and private providers should be treated the same with regard to shared care.
* Ideally, the provider should follow our local shared care protocols for our locally agreed medicines. However, we do accept the commissioning position of the provider, if this is reasonable.
* If an NHS provider or private provider requests shared care for medicines not on our local formulary, please seek advice from the ICB pharmacy and medicines optimisation team.
* If the provider organisation has their own shared care protocol, it would be a professional judgment call as to whether the primary care prescriber felt the shared care protocol was adequate and safe for the sharing of care. The ICB pharmacy and medicines optimisation team can advise.
* Extra considerations for private providers – For example, is the organisation CQC registered? Check <https://www.cqc.org.uk/>
* If the provider is not fulfilling their duties as part of the shared care protocol, please flag to the ICB pharmacy and medicines optimisation team.

## **What do we mean by 'primary care'?**

**The NHS definition of primary care is: *'Primary care services provide the first point of contact in the healthcare system, acting as the 'front door' of the NHS. Primary care includes general practice, community pharmacy, dental, and optometry (eye health) services.'***

**This document will refer to 'primary care' in its truest, widest sense. We acknowledge that, currently, most prescribing in primary care is completed by General Practice but we envisage the development of prescribing in all areas of primary care over the next few years.**

## **Full Rationale/Definitions of Traffic Light – Red Amber Green – 'RAG' Status**

## **Red Drugs**

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| **Red** | Specialist use only. The specialist\* initiates and continues all prescribing and completes all ongoing monitoring. |

**Red =** medications/therapies which are classified as suitable for prescribing and management only within specialist care settings, such as hospitals or specialist clinics. These drugs are not prescribed in primary care due to their complexity, potential for serious side effects, the need for specialised monitoring, the high level of expertise required to manage their use, or because of commissioning arrangements.

### **Key Characteristics of Red Drugs:**

1. **Specialist-Only Prescribing**:
* Prescribing responsibility remains solely with the specialist.
* General practitioners (GPs) or primary care providers do not prescribe or monitor these drugs.
1. **Complexity and Monitoring**:
* Red drugs often have significant risks or require specialised knowledge for safe administration.
* They may need close and frequent monitoring, which is beyond the scope of primary care.
1. **Limited Indications**:
* These drugs are typically used for specific, often rare, conditions.
* Examples include certain oncology medications, intravenous treatments, medications with strict safety protocols, medicines undergoing or included in clinical trials.
1. **High-Cost or Specialised Use**:
* Some red drugs are only available under specific schemes if provided by a specialist, for example, patient access schemes.
* Some require specialised administration methods (e.g., infusions).
* Some involve storage or handling requirements unsuitable for primary care.
* Some treatments are for rare, specialist indications and hence require expert knowledge for prescribing and administration.
1. **Examples of Red Drugs:**
* Specialist biologics – e.g. adalimumab, infliximab, rituximab
* Clozapine

### **Responsibilities for red drugs:**

* **Specialists**:
* Take full responsibility for prescribing, administering, and monitoring these medications.
* Provide detailed patient education on the medication’s use and potential side effects.
* Communicate effectively with other healthcare providers involved in the patient’s care.
* **Primary Care Providers**:
* Generally, do not prescribe or manage these drugs.
* May provide general care and support for the patient but refer any issues related to the red drug back to the specialist.
1. If the drug is prescribed on a long-term basis, add the red drug to the primary care clinical system as a 'specialist only or hospital only medicine' for information when prescribing other medicines. **A guide on how to do this is** [**here**](https://humberandnorthyorkshire.org.uk/wp-content/uploads/2025/04/S1_EMIS_Red-Drug-Recording-April-2025.docx)**.**
2. **Benefits of Red Drug Classification:**
* **Patient Safety**: Ensures complex or high-risk medications are managed by those with the necessary expertise.
* **Streamlined Care**: Clearly delineates responsibilities between primary and specialist care providers.
* **Resource Allocation**: Optimises the use of healthcare resources by keeping complex therapies in specialised settings.

### **Challenges of Red Drug Classification:**

* **Access Issues**: Patients may need to travel to specialist centres for ongoing treatment.
* **Coordination of Care**: Effective communication between specialists and primary care providers is essential to ensure holistic patient care.

By reserving these drugs for specialist use, the red drug classification aims to minimise risks and maximise the benefits for patients requiring complex or intensive treatment.

## **Amber Shared Care Protocol (Amber SCP)**

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| **Amber Shared Care Protocol (Amber SCP)** | Specialist initiation with ongoing monitoring. Medicines that must be initiated by a specialist\*, and which require significant monitoring on an ongoing basis.Full agreement to share the care of each specific patient must be reached under the shared care protocol (SCP), which must be provided to the primary care provider.If a commissioned SCP is not available, these must be treated as red. |

**Amber Shared Care drugs** are medications that are prescribed and monitored under a formal agreement between specialist healthcare providers (e.g., hospital consultants) and primary care providers (e.g., general practitioners, GPs).

This collaborative arrangement ensures that the responsibility for a patient's care, including prescribing and monitoring, is shared appropriately between healthcare settings.

### **Key Characteristics of Amber Shared Care Drugs:**

1. **Complexity of Treatment**:
* Shared care drugs are typically used to treat chronic or specialised conditions requiring expertise for initiation or dose adjustments.
* Examples include medications for rheumatology, oncology, neurology, or mental health conditions.
1. **Specialist Initiation**:
* Treatment is usually initiated and stabilised by a specialist in a secondary or tertiary care setting.
* Specialists ensure that the patient responds well to the medication before transferring care to the GP.
1. **Formal Shared Care Agreement**:
* A structured protocol or agreement outlines the responsibilities of both the specialist and the GP (or other primary care HCP).
* This includes details on prescribing, monitoring, communication, and patient follow-up.
1. **Ongoing Monitoring**:
* Certain shared care drugs require regular monitoring for efficacy and safety (e.g., blood tests to check for side effects or drug levels).
* The protocol specifies which provider is responsible for the monitoring.
1. **GP/Primary Care Prescribing**:
* Once the patient is stable and in agreement, primary care may take over routine prescribing, provided they feel confident in managing the medication.
* The specialist remains available for advice or consultation if issues arise.
* The patient is never discharged from the specialist as part of shared care arrangements.
1. **Examples of Shared Care Drugs**:
* Methotrexate: Used for rheumatoid arthritis or psoriasis, requiring regular blood monitoring.
* Lithium: Used for bipolar disorder, requiring serum level checks and kidney/thyroid function tests.

### **Benefits of Shared Care:**

* **Patient Convenience**: Allows patients to receive care closer to home while still benefiting from specialist oversight. Takes into account the best interest of the patient.
* **Resource Optimisation**: Balances the workload between primary and secondary care settings.
* **Continuity of Care**: Ensures patients have access to expertise and appropriate monitoring across their treatment journey.

### **Challenges of Shared Care:**

* **Clear Communication**: Effective communication is critical to avoid errors or lapses in monitoring.
* **Primary Care Clinician Confidence**: Primary Care must feel adequately trained and supported to take over prescribing and monitoring.
* **Protocol Adherence**: Both parties must adhere strictly to the shared care agreement for patient safety.

Shared care arrangements are designed to leverage the strengths of both primary and specialist care providers to optimise patient outcomes.

## **Amber Specialist Initiation (Amber SI)**

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| **Amber Specialist Initiation** **(Amber SI)** **Formerly known as Amber 2 in Humber** | Must be started by a specialist\* and remain with the specialist until the patient is stable on the new medicine but can then be transferred to primary care to continue prescribing without ongoing arrangements between the specialist and primary care. Primary care can refer back to the specialist at any time in relation to medication query, if required. |

**Amber Specialist Initiation Drugs** are medications that must be initially prescribed and stabilised by a specialist, but once the patient’s condition is stable, prescribing responsibility may be transferred to a primary care provider, such as a general practitioner (GP). These drugs typically require specialist expertise for initiation but can be safely managed in primary care once stable.

**Key Characteristics of Amber Specialist Initiation Drugs:**

1. **Specialist Responsibility for Initiation**:
* A specialist is responsible for diagnosing the condition, assessing suitability for the medication, and initiating treatment.
* The specialist ensures the patient is stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended.
* The specialist should provide the patient with enough medication to last until the GP Practice can take on the prescribing and advise the patient of this timescale.
1. **Primary Care Prescribing After Stabilisation**:
* Once the patient is stabilised on the medication, the GP/Primary Care may take over routine prescribing.
* There is no extra ongoing monitoring required and hence does not require a shared care protocol.
1. **Clear Protocols and Communication**:
* The specialist provides detailed guidance, including the drug regimen, monitoring requirements, and criteria for referral back to secondary care if needed.
* Regular communication ensures safe and effective continuity of care.
1. **Drugs Requiring Initial Monitoring and/or Specialist Knowledge**:
* These drugs often require specific expertise to manage risks or interpret initial monitoring results.
* After stabilisation, ongoing monitoring (e.g., blood tests) should be standard for primary care teams to complete.
1. **Examples of Amber SI Drugs**
* Antipsychotics, atogepant

### **Benefits of Amber Specialist Initiation Drugs:**

* **Expert Oversight**: Ensures that complex decisions, including dosing and management of side effects, are handled by specialists initially.
* **Safe Transition to Primary Care**: Patients benefit from receiving ongoing prescriptions closer to home once stabilised.
* **Cost-Effective and Resource-Efficient**: Allows primary care to manage stable patients while freeing specialist resources for new or complex cases.

### **Responsibilities of Amber Specialist Initiation Drugs:**

* **Specialists**:
* Initiate and stabilise treatment.
* Provide a clear plan and monitoring guidance to primary care.
* Remain available for advice or to take back prescribing if complications arise.
* **Primary Care Providers**:
* Continue prescribing according to the specialist’s guidance.
* Perform any required monitoring as per SPC/BNF.
* Refer back to the specialist if the patient’s condition changes or complications occur.

Amber Specialist Initiation Drugs strike a balance between ensuring specialist oversight during critical phases of treatment and leveraging the accessibility of primary care for long-term management.

## **Amber Specialist Recommendation – Amber SR**

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| --- | --- |
| **Amber specialist recommendation (Amber SR)**Formerly known as Amber 1 in Humber | Does not need to be initiated by a specialist but can be recommended by a specialist to primary care.No ongoing arrangements between the specialist and primary care. Primary care can refer back to the specialist at any time in relation to medication queries, if required. |

**Amber Specialist Recommendation** drugs are medications that a specialist recommends but do not necessarily need to initiate themselves. Instead, the prescribing responsibility lies with the primary care provider, often based on the advice and detailed guidance from the specialist.

### **Key Features of Amber Specialist Recommendation Drugs:**

1. **Specialist Assessment**:
* A specialist assesses the patient’s condition and determines the appropriateness of the medication.
* The specialist provides a recommendation for the medication but does not directly prescribe or initiate it.
1. **Primary Care Prescribing**:
* The GP or primary care provider prescribes the medication based on the specialist’s recommendation.
* This arrangement assumes the GP is comfortable with the prescribing and monitoring requirements.
1. **Support from Specialists**:
* The specialist supplies comprehensive guidance to the primary care provider, including:
	+ - Indication for use.
		- Dosage and administration instructions.
		- Monitoring requirements.
* The specialist remains available for advice or reassessment if needed.
1. **Simpler Monitoring Requirements**:
* Unlike drugs that require specialist initiation, Amber Specialist Recommendation drugs are usually safe for primary care to prescribe and monitor from the outset.
1. **Appropriate for Less Complex Medications**:
* These drugs are typically used in conditions where primary care has sufficient expertise to manage the treatment with specialist guidance.
1. **Examples for Amber SR Drugs**

Empagliflozin for heart failure, dexamethasone for endocrine disorders, brinzolamide.

### **Benefits of the Amber Specialist Recommendation System:**

* **Efficient Use of Resources**: Reduces the burden on specialists by enabling primary care to manage relatively straightforward cases.
* **Patient Convenience**: Ensures timely access to treatment through local primary care services.
* **Clear Accountability**: Provides clear delineation of responsibilities, with specialists offering guidance and GPs handling routine prescribing.

### **Responsibilities of the Amber Specialist Recommendation System:**

* **Specialists**:
* Evaluate the patient and provide a clear recommendation and rationale for the drug.
* Offer guidance on dosing, administration, and monitoring.
* Be available for consultation if questions or complications arise.
* Advise the patient on a reasonable timescale as to when they should be able to collect a prescription from their GP Practice for the new drug. This should be at least 14 days, it may take longer, to allow the GP Practice to process the specialist's letter and prepare the prescription.
* **Primary Care Providers**:
* Review the recommendation and prescribe if they are confident in managing the drug.
* Perform routine monitoring if needed and ensure adherence to the specialist’s guidance.
* Seek further advice or refer back to the specialist if the patient’s condition or treatment needs change.

Amber Specialist Recommendation drugs facilitate collaboration between primary and specialist care, ensuring patients benefit from specialist expertise while receiving ongoing treatment in a more accessible primary care setting.

## **Green Drugs**

|  |  |
| --- | --- |
| **Green with guideline (with LOCAL pathway/guideline)**Formerly known as Amber 1 in Humber | Can be prescribed in primary care and by specialist in line with a recommended LOCALLY approved pathway/guideline etc. |
| **Green** (no additional pathway/guideline) | Medicines suitable for routine use within primary care and secondary care.May be prescribed in primary care, as per the wording on the formulary and considering both the drug SPC and BNF. |

**Green Drugs** are medications that are deemed appropriate for initiation, prescribing, and management by either specialists or primary care. These drugs are typically straightforward to prescribe, have a well-established safety profile, and do not require specialist monitoring or expertise.

It should be noted that green drugs *may* be prescribed by primary care clinicians, this is on the basis that the generalist feels confident and competent to do so. There may still be occasions where a medicine is classified 'green' but an individual clinician does not feel comfortable taking on the prescribing of the drug. 'Green' classification is not a *must* be prescribed in primary care settings.

### **Key Characteristics of Green Drugs:**

1. **Primary Care Prescribing**:
* These medications can be prescribed by GPs and other primary care clinicians without the need for prior specialist involvement.
* The prescribing clinician assumes full responsibility for initiation, continuation, and monitoring.
1. **Low Complexity**:
* Green drugs are generally safe and well-tolerated.
* They have minimal and/or routine monitoring requirements, which can be managed within primary care settings.
1. **Commonly Used Medications**:
* These drugs are often used for the treatment of widely prevalent conditions that primary care teams routinely manage.
1. **Cost-Effectiveness**:
* They are typically cost-effective and included in standard formularies or guidelines.
1. **Examples of Green Drugs**

Inhalers for asthma and COPD, most antihypertensives, statins, etc.

### **Responsibilities when prescribing green drugs:**

* **Primary Care Providers**:
* Initiate treatment, monitor effectiveness, and manage any side effects or complications.
* Provide patient education on medication use, adherence, and potential risks.
* Adjust dosages as needed based on clinical judgment and patient response.
* **Specialists**:
* Generally, not involved in the prescribing or the management of green drugs unless complications arise.
* However, specialists may prescribe green drugs and may request primary care to prescribe green drugs.

### **Benefits of Green Drug Classification:**

* **Accessibility**: Patients can access treatment easily through primary care without needing specialist input.
* **Efficiency**: Frees up specialist resources for more complex cases while leveraging the expertise of GPs.
* **Patient Convenience**: Minimises delays in treatment and reduces the need for referrals or hospital visits.
* **Safety and Simplicity**: Green drugs have an established track record of safety and effectiveness for primary care management.

Green drugs are the backbone of primary care prescribing, supporting the effective and efficient management of common conditions within the community.

## **Other definitions**

## **HNY Medicines Related Shared Care and/or the Administration of Medicines Locally Enhanced Service**

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| --- |
| **Banding Definitions** |
|  The provider works within the shared care guidelines to undertake full monitoring of the patient.Monitoring, diagnostic tests and physical health checks include:  * All tests listed within the shared care guideline, including but not limited to ECG, respiratory function tests, weight, and BMI.
* Verbal interview and record-keeping of symptom checklist.
* Reporting of concerns to specialist.
* Adhering to primary care responsibilities as per shared care.

  |
| **Band 1: High-intensity monitoring**  |
| * Blood monitoring – 5+ times per year
* Diagnostic tests more than once per year
* Plus, any additional physical health checks

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| **Band 2: Intermediate monitoring** |
| * Blood monitoring – 3 - 4 times per year
* Diagnostic tests up to once per year
* Plus, any additional physical health checks

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| **Band 3: Infrequent monitoring**  |
|  * Blood monitoring – 1 - 2 times per year
* Plus, any additional physical health checks

   |
| **Band: Administration**  |
|  * Medicines listed within the locally enhanced scheme AND the administration of the medicine is by injection.

  |

**Ends**