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| **Growth hormone for**  **the treatment of growth failure in children**    **In accordance with South West London (SWL) Growth Hormone Commissioning Policy March 2025 (IMOC approved 26.03.2025)**  [**Commissioning – SW London Integrated Medicines Optimisation Committee (icb.nhs.uk)**](https://swlimo.southwestlondon.icb.nhs.uk/policies/commissioning/)  **Shared Care:**   * **1st choice:** Omnitrope® * **2nd choice:** Genotropin MiniQuick®, Genotropin GoQuick® or Genotropin® cartridges for pens   The above are also available via homecare, in addition to Norditropin FlexPro® and Ngenla® (somatrogon), as per the SWL Growth Hormone Commissioning Policy. | | |
| Approved by: South West London Integrated Medicines Committee (IMOC)  Approval date: 26.03.2025  Review Date: April 2027 (or sooner where appropriate) | | |
| **The content of this shared care protocol was correct as of March 2025. As well as this protocol, please ensure that** [**summaries of product characteristics**](https://www.medicines.org.uk/emc/) **(SPCs),** [**British national formulary**](https://bnf.nice.org.uk/?) **(BNF) or the** [**Medicines and Healthcare products Regulatory Agency**](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) **(MHRA) or** [**NICE**](https://www.nice.org.uk/) **websites are reviewed for up-to-date information on any medicine.** | | |
| **Specialist responsibilities**   * Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol ([section 2](#Two_indications)) and communicated to primary care. * Discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see [section 11](#Eleven_advice_to_patients)) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet. * Ensure that the patient/parents/carer is willing to administer injection and is comprehensively trained in administration technique before initiating shared care. * Arrange for the supply of appropriate injection device and needles. * Assess for contraindications and cautions (see [section 4](#Four_cx_and_cautions)) and interactions (see [section 7](#Seven_interactions)). * Conduct required baseline investigations and initial monitoring (see [section 8](#Eight_specialist_monitoring)). * Initiate and optimise treatment as outlined in [section 5](#Five_dosing). Prescribe the maintenance treatment for at least 4 months and until optimised. * Once treatment is optimised, complete the shared care documentation and send to patient’s GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information ([section 13](#Thirteen_specialist_contact)). * Prescribe sufficient medication (minimum 4 months) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. * Conduct the scheduled reviews and monitoring in [section 8](#Eight_specialist_monitoring) and communicate the results to primary care. After a review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. * Reassume prescribing responsibilities if a female becomes or wishes to become pregnant. * Provide advice to primary care on the management of adverse effects if required and review patient at the request of GP should any problems arise. * Liaise with local children’s endocrine nursing/community nursing or homecare nursing team on issues around injection technique and problems with injection sites. * Signpost family to support groups and information material. * Complete internal Blueteq forms if requested locally for internal monitoring purposes.   **Primary care responsibilities**   * Respond to the request from the specialist for shared care in writing within 14 days. * If accepted, prescribe ongoing treatment as detailed in the specialist’s request and as per section 5, taking into any account potential drug interactions in [section 7](#Seven_interactions). * Adjust the dose of treatment prescribed as advised by the specialist. * Conduct the required monitoring as outlined in [section 9](#Nine_primary_care_monitoring). Communicate any abnormal results to the specialist. * Manage adverse effects as detailed in [section 10](#Ten_ADRs_and_Management) and discuss with specialist team when required. * Stop treatment and make an urgent referral to the specialist if hypersensitivity reactions and/or anaphylaxis occur. * Refer the management back to the specialist if the patient becomes or plans to become pregnant. * Stop treatment as advised by the specialist.   **Patient and/or carer responsibilities**   * Take treatment as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist. * Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend. * Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in [section 11](#Eleven_advice_to_patients). * Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of growth hormone with their pharmacist before purchasing any OTC medicines. * Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant. | | |
| **1. Background** [Back to top](#Responsibilities) | | |
| Somatropin is a recombinant growth hormone of human sequence. It is a synthetic form of human growth hormone, a potent metabolic hormone that is essential for normal growth in children. Somatropin has replaced growth hormone of human origin (somatotrophin) and is licensed for use in adults and children. It is used in children to treat growth disturbance associated with growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, children considered small for gestational age with subsequent growth failure at 4 years or later, short stature homeobox-containing gene (SHOX) deficiency and Noonan syndrome.  Somatropin is a metabolic hormone with important effects on the metabolism of lipids, carbohydrates and proteins. It increases growth rate and stimulates linear growth in children by directly acting on the growth plates and by production of insulin-like growth factors, particularly IGF-1.  Somatragon works in a similar way to somatropin but it is a long-acting recombinant human growth hormone, providing a weekly injection instead of a daily one (as with all somatropin preparations).  These are biological medicines, and must be prescribed and dispensed by brand name. | | |
| **2. Indications\*** [Back to top](#Responsibilities) | | |
| **Omnitrope®(1st choice) and Genotropin® (2nd choice choice)**   * Growth hormone deficiency * Chronic renal insufficiency * Short stature homeobox (SHOX) (off-label use, agreed locally across SWL) * Small gestational age (SGA) * Prader-Willi syndrome * Turner syndrome   \*The only licensed somatropin product for Noonan syndrome is Norditropin FlexPro® which is NHSE commissioned (specialist centres only). This is available via the nearest commissioned specialist centre which is Evelina London Children's Hospital, as per the SWL Growth Hormone Commissioning Policy. | | |
| **3. Locally agreed off-label use** [Back to top](#Responsibilities) | | |
| Omnitrope® and Genotropin® are used off-label in children with SHOX in the absence of a licensed product for this indication, following the discontinuation of Humatrope®. | | |
| **4. Contraindications and cautions** [Back to top](#Responsibilities)  This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNFC](https://bnfc.nice.org.uk/drugs/somatropin/#indications-and-dose) & [SPC](https://www.medicines.org.uk/emc/search?q=somatropin) for comprehensive information. | | |
| **Contraindications:**   * Injections containing benzyl alcohol in neonates * Discontinue at time of renal transplantation * Evidence of tumour activity (complete antitumour therapy and ensure intracranial lesions inactive before starting) * Not to be used for growth promotion in children with closed epiphyses (or near closure in Prader-Willi syndrome) * Severe obesity in Prader-Willi syndrome * Severe respiratory impairment in Prader-Willi syndrome * Hypersensivity to the active substance or excipients   **Cautions:**   * Diabetes mellitus (adjustment of antidiabetic therapy may be necessary) * Disorders of the epiphysis of the hip (monitor for limping) * History of malignant disease * Hypoadrenalism (initiation or adjustment of glucocorticoid replacement therapy may be necessary) * Initiation of treatment close to puberty not recommended in child born small for corrected gestational age * Papilloedema * Resolved intracranial hypertension (monitor closely) * Risk of hypothyroidism—manufacturers recommend periodic thyroid function tests * Silver-Russell syndrome | | |
| **5. Initiation and ongoing dose regime** [Back to top](#Responsibilities)   * Transfer of monitoring and prescribing to primary care is normally after the patient’s dose has been optimised and with satisfactory investigation results for at least 4 months * The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. * All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician * Termination of treatment will bethe responsibility of the specialist. | | |
| The loading period and initial maintenance dose must be prescribed by the initiating specialist.  The dosage and administration of growth hormone treatment should be tailored to the needs of each individual child, but the recommended doses as per the SPC and NICE are below.  **Initial stabilisation and maintenance dose:**  **Growth hormone deficiency (GHD):**   * Omnitrope® and Genotropin®:0.025– 0.035 mg/kg daily or 0.7–1.0 mg/m² daily   **Chronic renal insufficiency (CRI):**   * Omnitrope® and Genotropin®: 0.045–0.050 mg/kg daily or 1.4 mg/m² daily * A dose correction can be needed after six months of treatment.   **Short stature homeobox (SHOX) (off-label use, agreed locally across SWL):**   * Omnitrope® and Genotropin® (off-label use): 0.045–0.050 mg/kg daily   **Small gestational age (SGA):**   * Omnitrope® and Genotropin®: 0.035 mg/kg daily or 1.0 mg/m² daily   **Prader–Willi syndrome:**   * Omnitrope® and Genotropin®: 0.035 mg/kg daily or 1.0 mg/m² daily (maximum of 2.7 mg daily)   **Turner syndrome:**   * Omnitrope® and Genotropin®: 0.045–0.050 mg/kg daily or 1.4 mg/m² daily   **Conditions requiring dose adjustment:**  See section 8. | | |
| **6. Pharmaceutical aspects** [Back to top](#Responsibilities) | | |
| Route of administration: | Subcutaneous injection | |
| Formulation: | * **Omnitrope®:** 5mg/1.5ml, 10mg/1.5ml and 15mg/1.5ml solution for injection cartridges * **Genotropin MiniQuick®:** 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg powder and solvent for solution for injection pre-filled disposable devices * **Genotropin GoQuick®:** 5.3mg and 12mg powder and solvent for solution for injection pre-filled pens * **Genotropin® cartridges for pens:** 5.3mg and 12mg powder and solvent for solution for injection cartridges | |
| Administration details: | Subcutaneous injection sites should be rotated to prevent lipoatrophy.  Refer to the Summary of Product Characteristics for the specified brand for administration instructions. | |
| Other important information: | * **Product choice:** There are no significant therapeutic differences between the preparations but choice may be determined by patient preference, dose requirements, product in-use expiry, product presentation, and licensed indications. * **Storage:** Refer to the Summary of Product Characteristics for the specified brand. * **Reconstitution:** Refer to the Summary of Product Characteristics for the specific brand. * Brands should only be changed by the Consultant/Specialist centre since training in a new injection technique may be required. | |
| **7. Significant medicine interactions** [Back to top](#Responsibilities)  The following list is not exhaustive. Please see [BNFC](https://bnfc.nice.org.uk/drugs/somatropin/#indications-and-dose) or [SPC](https://www.medicines.org.uk/emc/search?q=somatropin) for comprehensive information and recommended management. | | |
| * **Compounds metabolised by cytochrome P450 isoenzymes:** Limited evidence suggests that somatropin may increase the clearance of compounds known to be metabolised by cytochrome P450 isoenzymes. The clearance of compounds metabolised by cytochrome P450 3A4 (eg. sex steroids, corticosteroids, anticonvulsants and ciclosporin) may be especially increased resulting in lower plasma concentrations of these compounds. The clinical significance of this is unknown. * **Glucocorticoid therapy:** May inhibit growth-promoting effects of somatropin. * **High doses of androgens, oestrogens or anabolic steroids:** Can accelerate bone maturation and may diminish gain in final height. * **Insulin:** Somatropin can induce insulin resistance; insulin doses may have to be adjusted in diabetic patients receiving concomitant somatropin. | | |
| **8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist** [Back to top](#Responsibilities)  Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care. | | |
| **Baseline investigations and initial monitoring:**   * Height * Weight * Calculation of growth velocity * IGF-1 * TFT * HbA1c * Fasting insulin (may not be routinely required) * Glucose   *Clinical practice may vary*  **Monitoring following dose changes:**   * In children and young people with diabetes, close monitoring and anti-diabetic therapy might require adjustment when somatropin is initiated. * There may be a reduction in serum T4 and an increase in serum T3 concentrations. It is particularly advisable to test thyroid function after starting treatment and after dose adjustments. * **Chronic renal insufficiency:** Monitoring of renal function will be jointly coordinated with Paediatric Nephrologists (usually Guy’s or GOSH).   **Ongoing monitoring and follow up:**   * **4-6 monthly clinical review** with height and weight, including calculation of growth velocity. Frequency of monitoring may vary depending on clinical response and medical background. * **Annual review by specialist\*** with hand X-ray for bone age and biochemical analysis: IGF-1, TFT, HbA1c, fasting insulin (may not be routinely required) and glucose. (\*Clinical practice may vary) * Growth hormone deficiency secondary to a malignant disease should be examined frequently for progression or recurrence of the underlying disease process. * Review of injection techniqueby specialist Paediatric Endocrine Nurse or Children’s Community Nurse to ensure accuracy and adherence. * **Turner syndrome:**   1) Increased risk of developing primary hypothyroidism associated with anti-thyroid antibodies (affecting response to somatropin); treat with replacement thyroid hormone if indicated.  2) Monitor growth of hands and feet and if increased growth observed, a dose reduction to the lower part of the dose range should be considered.  3) Patients have an increased risk of otitis media; periodic otological evaluation is recommended.   * **Chronic renal insufficiency:**   1) Monitoring of renal function will be jointly coordinated with Paediatric Nephrologists (usually Guy’s or GOSH).  2) Monitor for progression of renal osteodystrophy.   * **Prader-Willi syndrome:** Monitor for scoliosis by clinical examination yearly. Scoliosis may progress in any child during rapid growth; monitor for signs during treatment. * **Small for gestational age:** IGF-1 should be measured twice a year following initiation of somatropin, and if elevated the IGF-I / IGFBP-3 ratio could to taken into account to consider dose adjustment.   When a patient is reviewed, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 9](#Nine_primary_care_monitoring) remains appropriate. | | |
| **9. Ongoing monitoring requirements to be undertaken by primary care** [Back to top](#Responsibilities)  See [section 10](#Ten_ADRs_and_Management) for further guidance on management of adverse effects/responding to monitoring results. | | |
| **Monitoring** | | **Frequency** |
| Monitor patient’s overall health and wellbeing | | 6-12 monthly |
| Monitor for any adverse effects and refer to the specialist if required | | 6-12 monthly |
| **Prader-Willi Syndrome:**   * Concordance to a calorie-restricted diet * If signs of upper airway obstruction (including onset of or increased snoring), treatment should be interrupted and ENT assessment performed. * Monitor if sleep apnoea suspected * Monitor for signs of respiratory infection, which should be diagnosed as early as possible and treated aggressively. * Weight; initiate weight control measures if necessary. | | 6-12 monthly |
| **10. Adverse effects and other management** [Back to top](#Responsibilities)  **Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  For information on incidence of ADRs see relevant summaries of product characteristics | | |
| **Result** | | **Action for primary care** |
| **As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance** | | |
| Headache, visual problems, nausea and/or vomiting  Benign intracranial hypertension | | Assess urgently to rule out benign intracranial hypertension.  Organise fundoscopy for papilloedema; if confirmed, a diagnosis of benign intracranial hypertension should be considered and if appropriate, refer to specialist for treatment to be discontinued. |
| Transient local skin reactions at injection site | | Vary site of injection and refer back to specialist if troublesome. |
| Peripheral oedema, arthralgia, myalgia, carpel tunnel syndrome | | Refer to specialist |
| Myositis | | Possibly related to the preservative metacresol (Genotropin® cartridges and GoQuick only). Consider myositis if myalgia/ disproportionate pain at the injection site and, if confirmed, a somatropin presentation without metacresol should be used. Refer to specialist. |
| Leukaemia | | Immediate hospital attention |
| Slipped femoral epiphyses | | Examine the child clinically if limping and refer to specialist |
| Rash, urticaria, pruritis | | Refer to specialist; stop if hypersensitivity reaction or anaphylaxis |
| Numbness/tingling | | Refer to specialist |
| Hypothyroidism | | Refer to specialist |
| Type 2 diabetes mellitus | | Refer to specialist |
| Gynaecomastia | | Refer to specialist |
| Pancreatitis | | Refer to specialist |
| **11. Advice to patients and carer** [Back to top](#Responsibilities)  The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines. | | |
| **The patient should be advised to report any of the following signs or symptoms to their specialist without delay:**   * Persistent headache, visual problems, nausea, vomiting * Persistent thirst, passing excessive urine * Persistent abdominal pain * Pain in hip or limp * Persistent pain in joints * Redness or inflammation at the site of injection   **Patient information:**  Child Growth Foundation: <https://childgrowthfoundation.org/conditions/>  British Society for Paediatric Endocrinology and Diabetes: <https://www.bsped.org.uk/media/1968/pros-and-cons-of-gh-treatment.pdf>  European Society for Paediatric Endocrinology: <https://www.eurospe.org/publications/patient-booklets/> | | |
| **12. Pregnancy, paternal exposure and breast feeding** [Back to top](#Responsibilities)  It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist. | | |
| **All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.**  **Pregnancy:**  There is no or limited data from the use of somatropin in pregnant women and animal studies are insufficient. Somatropin is not recommended during pregnancy and in women of childbearing potential not using contraception. It should be discontinued if pregnancy occurs.  **Breastfeeding:**  There have been no clinical studies to assess the safety of somatropin in breastfeeding women. It is not known if somatropin is excreted into breast milk, however absorption from milk is unlikely. Caution should be exercised if somatropin is used in breast feeding women.  **Paternal exposure**:  Fertility studies with somatropin have not been performed. | | |
| **13. Specialist contact information** [Back to top](#Responsibilities) | | |
| Name: *insert name*  Role and specialty: *insert role and speciality*  Daytime telephone number: *insert daytime telephone number*  Email address: *insert email address*  Alternative contact: *insert contact information, e.g. for clinic or specialist nurse*  Out of hours contact details: *insert contact information, e.g. for duty doctor* | | |
| **14. Additional information** [Back to top](#Responsibilities) | | |
| Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. | | |
| **15. References** [Back to top](#Responsibilities) | | |
| * BNF for Children. Available at: [BNFC](https://bnfc.nice.org.uk/drugs/somatropin/#indications-and-dose) [Accessed 11/11/2024] * Electronic Medicines Compendium (2023) Omnitrope Summary of Product Characteristics. Available at: [Omnitrope](https://www.medicines.org.uk/emc/product/12506/smpc) [Accessed 11/11/2024] * Electronic Medicines Compendium (2024) Genotropin Summary of Product Characteristics. Available at: [Genotropin](https://www.medicines.org.uk/emc/product/3432/smpc) [Accessed 11/11/2024] * NICE (2010) Technology appraisal guidance 188. Human growth hormone (somatropin) for the treatment of growth failure in children. Available at: <https://www.nice.org.uk/guidance/ta188> [Accessed 11/11/2024] * BSPED Growth Disorders Special Interest Group (2023) Shared care guidelines for paediatric use of daily and long-acting recombinant human growth hormone. Available at: <https://www.bsped.org.uk/media/alxow2wv/gh-shared-care-guidelines-20240206.pdf> [Accessed 11/11/2024] * SWL Growth Hormone Commissioning Policy, March 2025 [Commissioning – SW London Integrated Medicines Optimisation Committee](https://swlimo.southwestlondon.icb.nhs.uk/policies/commissioning/) | | |
| **16. Other relevant national guidance** | | |
| * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/> * NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/> * General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care> * NICE NG197: Shared decision making. Last updated June 2021. [National](https://www.nice.org.uk/guidance/ng197/) Guideance 197. | | |
| **17. Local arrangements for referral** [Back to top](#Responsibilities)  Define the referral procedure from hospital to primary care prescriber & route of return should the patient’s condition change. | | |
| Follow place based processes. | | |

**Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)**

Dear *insert Primary Care Prescriber's name*

Patient name: *insert patient's name*

Date of birth: *insert date of birth*

NHS Number*: insert NHS Number*

Diagnosis: *insert diagnosis*

As per the agreed SWL shared care protocol for *insert medicine name* for the treatment of *insert indication,* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

|  |  |
| --- | --- |
|  | **Specialist to complete** |
| *The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:* |  |
| *Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory* | *Yes / No* |
| *The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care* | *Yes / No* |
| *The risks and benefits of treatment have been explained to the patient* | *Yes / No* |
| *The roles of the specialist/specialist team/* *Primary Care Prescriber / Patient and pharmacist have been explained and agreed* | *Yes / No* |
| *The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments* | *Yes / No* |
| *I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)* | *Yes / No* |
| *I have included with the letter copies of the information the patient has received* | *Yes / No* |
| *I have provided the patient with sufficient medication to last until* |  |
| *I have arranged a follow up with this patient in the following timescale* |  |

Treatment was started on *insert date started* and the current dose is *insert dose and frequency*.

If you are in agreement, please undertake monitoring and treatment from *insert date* NB: date must be at least 4 months from initiation of treatment.

The next blood monitoring is due on *insert date* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

**Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)**

**Primary Care Prescriber Response**

Dear *insert Doctor's name*

Patient: *insert Patient's name*

NHS Number : *insert NHS Number*

Identifier: *insert patient's date of birth and/or address*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

|  |  |  |
| --- | --- | --- |
| Medicine | Route | Dose & frequency |
|  |  |  |

I can confirm that I am willing to take on this responsibility from *insert date* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_

Primary Care Prescriber address/practice stamp

**Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)**

**Re:**

Patient: *insert Patient's name*

NHS Number : *insert NHS Number*

Identifier: *insert patient's date of birth and/or address*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS SWL ICB in conjunction with local acute trusts have classified *insert medicine name* as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

**I regret to inform you that in this instance I am unable to take on responsibility due to the following:**

|  |  |  |
| --- | --- | --- |
|  |  | **Tick which apply** |
| **1.** | **The prescriber does not feel clinically confident in managing this individual patient’s condition, and there is a sound clinical basis for refusing to accept shared care**  As the patients primary care prescriber I do not feel clinically confident to manage this patient’s condition because *insert reason*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.  **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.** |  |
| **2.** | **The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement**  As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.  **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you** |  |
| **3.** | **A minimum duration of supply by the initiating clinician**  As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.  ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.*** |  |
| **4.** | **Initiation and optimisation by the initiating specialist**  As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.  ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.*** |  |
| **5.** | **Shared Care Protocol not received**  As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.***  For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.  ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.*** |  |
| **6.** | **Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)** |  |

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

**Primary Care Prescriber signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

**Primary Care Prescriber address/practice stamp**