Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in-date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version.

Patient Group Direction

for the administration of

Salbutamol 2.5mg/2.5 ml and 5mg/2.5ml nebulised solution

for emergency treatment of acute exacerbations of asthma in patients from 2 years old or acute exacerbation of respiratory symptoms in adults

by registered healthcare professionals

in

Powys Teaching Health Board

Version number: PGD 0046C

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Local Health Board

Reference Number: PGD 0046C
Valid from: 12/02/2024
Review date: 12/02/2026
Expiry date: 12/02/2027

Change history

Version number	Change details	Date
PGD0046.	Initial version	September 2010
PGD0046A	Review	21/11/2016
PGD0046B	Review and extension of settings, and of professionals using PGD	01/03/2021
PGD0046C	Review in line with references – minor changes to format to promote consistency with other PTHB PGDs	12/02/2024

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	2/7/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	2/8/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB- Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	2/8/2024
Senior Representative of Professional Group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche FC9C4C63FC374A7...	2/7/2024

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation.

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) Practitioners must also fulfil the additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Initial training	• The administration of salbutamol 2.5mg/2.5ml and 5mg/2.5ml nebuliser solution and knowledge of its uses, contraindications and adverse effects Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for administration of medicines. Recommended training eLfH PGD elearning programme. PTHB staff to access via ESR. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills. • must have completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 2 safeguarding or the equivalent. • must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. • must be familiar with salbutamol nebules and alert to changes in the BNF (https://bnf.nice.org.uk) and Summary of Product Characteristics • must have access to the Patient Group Direction and associated online resources **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Competency assessment	• Evidence of ongoing PGD training to be submitted to Line Manager annually. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competency in their Personal Appraisal and Development Review (PADR). • Evidence of training in ILS, anaphylaxis and safeguarding.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Updating at least every 2 years on the use of PGDs and salbutamol nebulised solution • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. • Evidence of ongoing / refresher training to be submitted to line manager annually. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD. The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.**

Clinical condition

Clinical condition or situation to which this PGD applies	• Emergency treatment of acute (moderate and severe) or life-threatening exacerbation of asthma in patients 2 years of age and over, or acute exacerbation of respiratory symptoms in adults (symptoms suggesting acute reversible airways obstruction in adults with known COPD), whilst awaiting medical assistance • May be administered in conjunction with ipratropium nebuliser solution for the treatment of reversible airways obstruction (PGD0167 Ipratropium bromide 250 micrograms in 1 ml and Ipratropium bromide 500 micrograms in 2 ml nebuliser solution).

	NB Patients should be managed in line with NICE/ MIU guidelines. **It is the responsibility of the administering practitioner to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**

Inclusion criteria	• Patient aged 2 years or over requiring emergency treatment of acute (moderate and severe) or life threatening exacerbation of asthma (Refer to Appendix B (Adults) and Appendix C (Children) for a full list of symptoms and severity of exacerbation of asthma)
	OR
	• Adult patient with acute exacerbation of respiratory symptoms (symptoms suggesting acute reversible airways obstruction in adults with known COPD), presenting with:
	  ○ Acute onset of a sustained worsening of symptoms beyond the patients' usual day-to-day variation: commonly reported symptoms include:
	  ▪ Worsening breathlessness
	  ▪ Cough
	  ▪ Increased sputum production
	  ▪ Change in sputum colour
	  ▪ Wheeze
	  ▪ Fever without an obvious source
	  ▪ Upper respiratory tract infection in the past 5 days
	  ▪ Increased respiratory rate or heart rate increase 20% above baseline.
	
	IMPORTANT: patients with severe or life-threatening asthma attacks may not appear distressed and may not display all of the symptoms. The presence of ANY symptom should alert the practitioner to act. Regard each emergency consultation as being for severe acute asthma until shown otherwise.
	
	• Medical and drug history taken, no reason for exclusion
	• Informed consent, from the individual or a person legally able to act on their behalf, must be obtained for administration and recorded appropriately. The patient information leaflet should be available to inform consent. Where a person lacks capacity, in accordance with the Mental Capacity Act 2005, a decision to treat may be made in the individual's best interests. NB Refer to PTHB Consent to Treatment and Examination Policy. The individual should be informed they are being treated using a PGD.

	Consent to treatment - if the patient is unable to give consent due to a life-threatening situation, or if parent/guardian/carer is not present, salbutamol should be administered where treatment is judged to be in the best interests of the patient. In case of any doubt, contact medical team or emergency services.
Exclusion criteria	• Under 2 years of age • Known allergy or hypersensitivity to salbutamol or any of the excipients listed in the SPC -see www.medicines.org.uk • Refusal of treatment/ no valid consent, if able to give consent. Refer to section 'action to be taken if the individual or carer declines treatment' • Contraindications listed in SPC and BNF • Conditions outside of the clinical situations criteria such as breathlessness caused by physical obstruction caused by a foreign body, heart failure or pneumothorax • Refer to section 'action to be taken if the individual is excluded'
Cautions	**NB. Cautions listed are only for non-life-threatening situations.** Where a caution is present the practitioner should be aware of the possible effects of administration but should continue to administer where the benefit outweighs risk. • Pregnancy or breastfeeding • Hyperthyroidism • Thyrotoxicosis • Underlying heart disease (severe heart failure, ischaemic heart disease, arrythmia): patients should be advised to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. • Diabetes (requires blood glucose monitoring) • Patient known to receive large doses of other sympathomimetic drugs • Patient taking non-selective beta-blockers (i.e. propranolol) • Potentially serious hypokalaemia may result from beta-2 agonist therapy. Particular caution is advised in patients with acute severe asthma as hypokalaemia may be potentiated in hypoxic patients and those treated with xanthine derivatives, steroids, diuretics. See BNF for list of other medicines which may contribute to hypokalaemia. Serum potassium levels should be monitored in such situations • Hypertension

	• Salbutamol is predicted to increase the risk of digoxin toxicity when given with digoxin. Manufacturer advises caution • Salbutamol is predicted to increase the risk of elevated blood pressure when given with Linezolid (Manufacturer advises avoid) • Rasagiline (Manufacturer advises avoid), Selegiline (Manufacturer advises avoid) and Safinamide (Manufacturer advises caution). • Lactic acidosis has been reported in association with high therapeutic doses of nebulised short-acting beta-agonist therapy. • As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator • A small number of cases of acute angle-closure glaucoma have been reported in patients treated with a combination of nebulised salbutamol and ipratropium bromide. A combination of nebulised salbutamol with nebulised anticholinergics should therefore be used cautiously. Patients should receive adequate instruction in correct administration and be warned not to let the solution or mist enter the eye • Refer to BNF/SPC for complete information • Discuss with appropriate medical/ independent non-medical prescriber if the individual has multiple allergies, or any medical condition or medication of which the healthcare professional is unsure or uncertain. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads

Arrangements for referral for medical advice	**Seek medical or paramedic support for all patients** • Bronchodilation should not be the only or main treatment for patients with severe, unstable or life-threatening asthma. Medical and urgent paramedic support should always be requested (dial 999). Document actions taken. • Children with severe or life-threatening asthma should be transferred to hospital urgently. • Consider the need for immediate transfer to hospital, in line with NICE CKS and BTS/ SIGN 158 British Guideline on the Management of Asthma. BTS guidelines. • If attack resolved, inform the individual's GP, to enable review assessment to be held within 2 working days. • If there is poor response to the initial dose of salbutamol, and where appropriate, subsequent dose should be considered. Nebulised ipratropium bromide (PGD0167) should also be considered, if appropriate.
Action to be taken if individual excluded	If the patient is excluded from treatment under this PGD: • If salbutamol contraindicated, consider and refer to PGD0167 (Ipratropium nebuliser solution) • Transfer to emergency services/medical support - call ambulance immediately (dial 999). Use a pulse oximeter to monitor blood oxygen levels; administer oxygen to maintain SpO_2 in target range. Where appropriate, encourage patient to use their reliever medication through a spacer device. • Explain reason to patient/carer and document in the consultation record.
Action to be taken if the individual declines treatment	• Explain consequences of refusing treatment, discuss alternative sources of treatment. • Refer to a medical practitioner without delay/call 999 as appropriate • Document refusal and advice given in patient's record/Discharge Against Advice Form • Inform or refer to GP/follow local procedures as appropriate. Where appropriate, complete the letter on the WPAS system and send to the GP.

Details of the medicine

Name, form and strength of medicine	Salbutamol 2.5 mg/2.5 ml nebuliser solution Salbutamol 5 mg/2.5 ml nebuliser solution
Legal category	Prescription-only medicine (POM)
Off-label use	Salbutamol nebules are licensed in adults, adolescents and children aged 4 to 11 years. Use in children between 2 years

	and 4 years may be outside of the manufacturer's marketing authorisation but is consistent with advice in the BTS/SIGN asthma guideline. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product license.
Route/method of administration	Salbutamol Nebuliser Solution should be administered by a suitable nebuliser, via a face mask or T piece or via an endotracheal tube. **Asthma** The nebuliser should be oxygen driven (flow rate of 6L/min)(If an oxygen-driven nebulizer is unavailable, deliver by air-driven nebuliser, although be alert that oxygen desaturation may occur). **COPD** If a patient is hypercapnic or acidotic the nebuliser should be driven by compressed air, not oxygen (to avoid worsening hypercapnia). If oxygen therapy is needed, it should be administered simultaneously by nasal cannulae. Nebules must only be used by inhalation, to be breathed in through the mouth, and must not be injected or swallowed. Nebulisers should be used in a well ventilated room as it is usual for some nebulised drug to be released into the local environment.

Dose and frequency	• Children aged 2 to 5 years: ONE 2.5mg nebule
	• Children aged 5-11 years:
	  ○ for moderate severity: 2.5mg (ONE 2.5mg nebule)
	  ○ for severe asthma: 5mg (ONE 5mg nebule)
	• Children over 12 years and adults: ONE 5mg nebule
	
	• The onset of action of nebulised salbutamol is rapid, and improvement should be seen within 5 minutes of starting treatment. The effects of treatment should last for 4 to 6 hours.
	• Monitor and reassess the clinical response for 15-30 minutes for all patients
	• A second dose may be administered after 20 to 30 minutes, if medical or paramedic assistance is delayed and if symptoms do not improve or worsen (NB. see adverse effects – risk of paradoxical bronchospasm- if suspected, discontinue salbutamol immediately).

	• For all patients with life-threatening asthma or severe exacerbation with poor response and if symptoms persist despite initial salbutamol treatment consider, if appropriate, treatment with ipratropium (refer to PGD0167 Ipratropium nebuliser solution) and/or arrange immediate transfer to hospital.
Quantity to be administered	See above dose.
Maximum or minimum treatment period	When administered in an emergency, a second dose may be administered after 20-30 minutes if medical assistance is delayed and it is necessary. Total of **two** doses only.
Storage	• Store in the original package to protect from light • Replace unused nebules back into the foil over-wrap and place them back into their box. • Use the ampoules within 3 months of first opening the foil over-wrap. • Nebules should be opened immediately before use and any solution remaining after use should be discarded in accordance with local requirements
Drug interactions	All concomitant medications should be checked for interactions. A detailed list of drug interactions is available in the BNF https://bnf.nice.org.uk and SPC http://www.medicines.org.uk Refer to a prescriber if any concern of a clinically significant drug interaction.
Identification and management of adverse effects	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk. The following possible adverse effects are commonly reported with salbutamol nebules (≥1/100): • Tachycardia. • Tremor (usually hands), headache. Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. In this situation the salbutamol should be discontinued immediately, and the patient assessed to consider treatment with a different fast-acting bronchodilator.

	Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse are very rare. In the case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available. In case of anaphylaxis:- • Refer to adrenaline PGD 0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available, dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked allergic to **salbutamol** • The patient may be advised to wear a Medic Alert or similar device to alert other healthcare providers • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. • Record all adverse drug reactions (ADRs) in the patient's medical record and the individual's GP should be informed. • All significant adverse drug reactions should be reported via the Once for Wales Reporting System.
Records to be kept	Record consultation details as required by local procedures. In addition, record: • Relevant past and present medical and drug history taken, including any allergies and previous adverse events • Name of the patient, address, date of birth and GP with whom the patient is registered • Any reasons for exclusion or referral, including actions taken and any referral arrangements made. • Any advice received from medical cover and advice given to patient / carer, including advice given if excluded or declines treatment • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • That valid informed patient consent to treatment was obtained. Record name of representative who gave consent if appropriate.

	• Any administration outside the terms of the product marketing authorisation • That the drug is being administered in accordance with a PGD- record PGD number and version. For <u>administration</u>, record: • Date and time of administration. • Name, form, strength and dose of drug administered. • Route of administration • Expiry date(s) • Details of any adverse reactions and actions taken. The record must include the printed name and signature (or a password controlled e-records) of the healthcare professional responsible for administration. The record must be kept securely for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy.

Patient information

Written and verbal information to be given to patient or carer	• Explain course of action • Supply patient information leaflet and draw patient/representative's attention to this information • Explain mode of action, risks and benefits of the medicine, possible side effects and their management. • After stabilisation of acute exacerbation of asthma, advise individual/carer to use their short-acting beta-2 agonist up to 4 times a day (not exceeding 4-hourly) as directed • Give appropriate advice if medication is used off-label
Follow-up advice to be given to patient or carer	• All patients with a resolved asthma attack should be referred to GP for review assessment within 2 working days • Advise patient/representative to: o seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact GP via surgery or emergency on-call service o seek advice from asthma nurse or GP when using salbutamol regularly, or if short-acting relief bronchodilator treatment becomes less effective or more inhalations than usual are required.

	• Patients (or their carers) who have been using a nebuliser at home without specialist management should contact their GP about referral to a specialist. • If appropriate, advise to monitor the peak flow readings with peak flow meter • NB Seek medical or paramedic support for all patients. Arrange admission to hospital for all patients with features of a life-threatening asthma exacerbation, those with any features of a severe asthma attack persisting after initial bronchodilator treatment, or people with a moderate asthma exacerbation with worsening symptoms despite initial bronchodilator treatment and/or who have had a previous near-fatal asthma attack, or those who require a lower threshold for admission.

Key references

- British National Formulary (BNF) – online: https://bnf.nice.org.uk/drugs/salbutamol/, accessed November 2023
- BNFc online: https://bnfc.nice.org.uk/drugs/salbutamol/ accessed November 2023
- Salbutamol 2.5mg/2.5ml nebuliser solution, Cipla
    - Summary of Product Characteristics, last updated 24/01/2022
    - PIL, last updated June 2021
- Salbutamol 5mg/2.5ml nebuliser solution, Cipla
    - Summary of Product Characteristics, last updated 24/01/2022
    - PIL, last updated June 2021
- CKS: Scenario: acute exacerbation of asthma. Last revised August 2023
- CKS: Scenario: Acute exacerbation of chronic obstructive pulmonary disease. Last revised September 2023.
- BTS/ SIGN 158 British Guideline on the Management of Asthma. Updated July 2019
- NICE guideline [NG115]: Chronic obstructive pulmonary disease in over 16s: diagnosis and management Published date: December 2018 Last updated: July 2019
- NICE QS25: Quality standard for asthma. Last updated 2018
- All Wales paediatric asthma management and prescribing guideline. AWMSG. June 2023
- All Wales Guideline for the Acute management of asthma and wheeze in children aged > 2 years. Accessed 21/11/23. Respiratory Health Implementation Group, Paediatric Respiratory Medicine, UHW, Cardiff
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

Appendix A Staff Accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP Practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager may wish to use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes. This list should be kept by PTHB, or the provider organisation adopting this PGD, for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in "comments"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

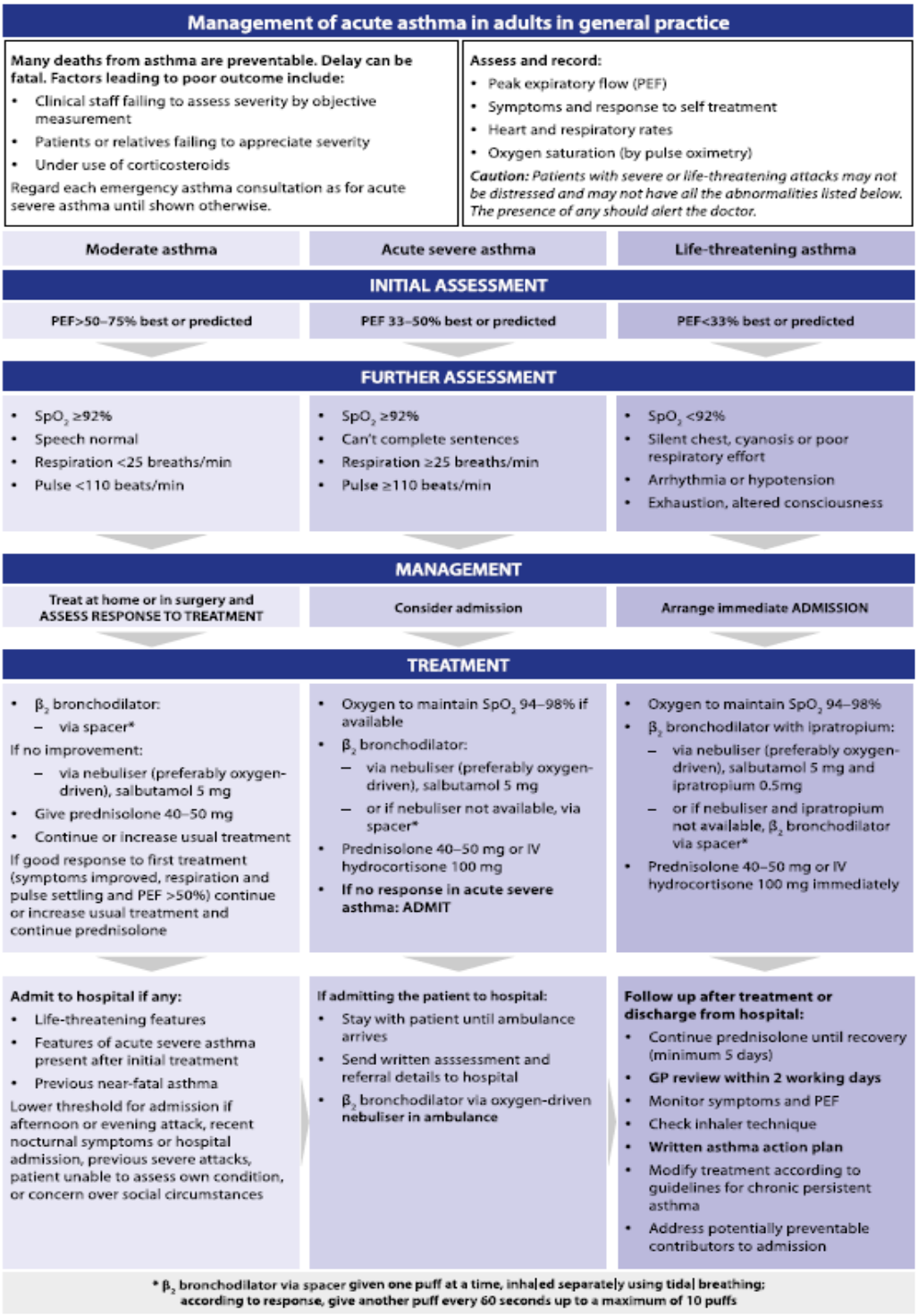
Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

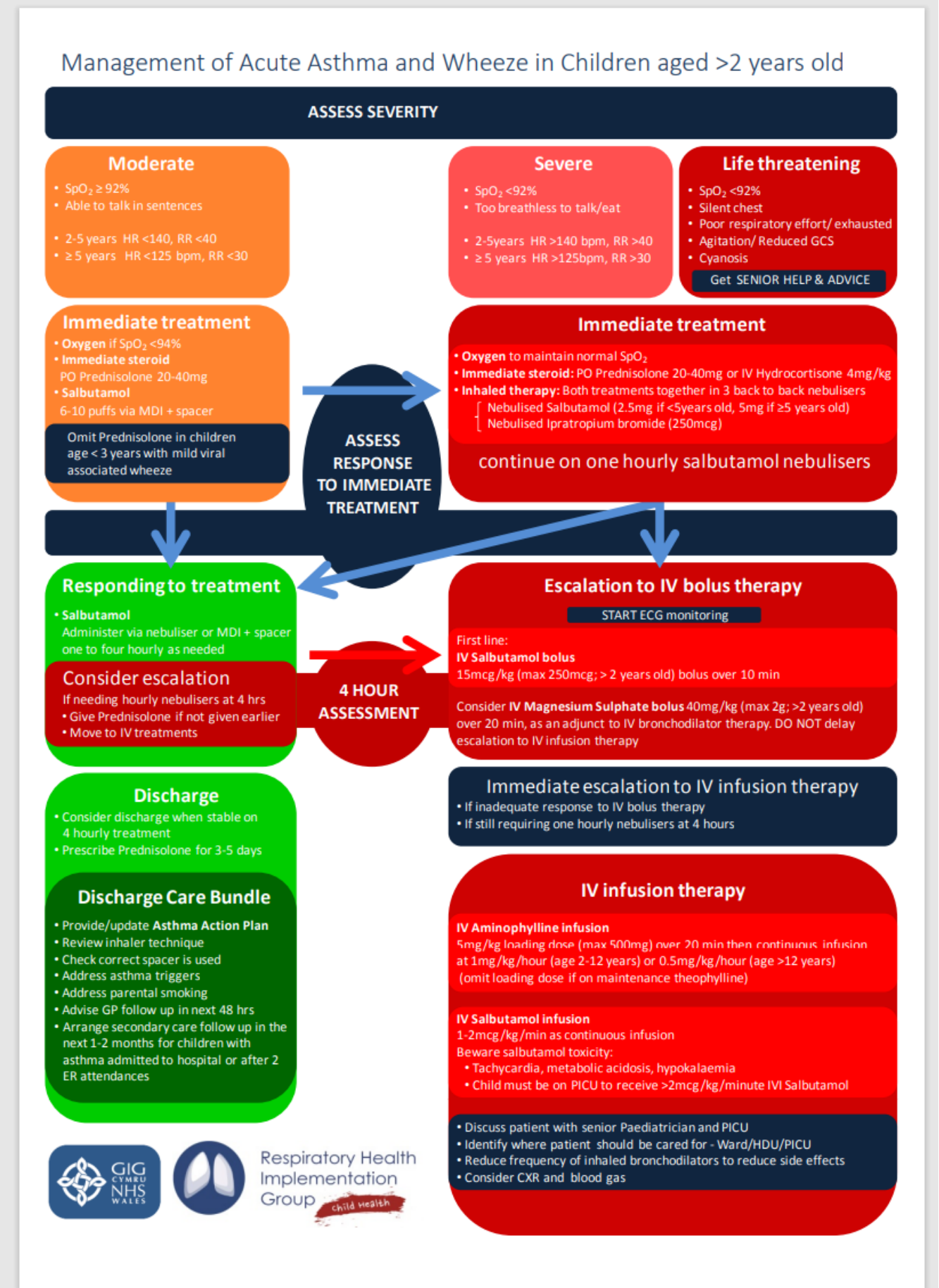
Appendix B:

Management of acute asthma in adults in general practice (Sign 158)

Annex 3



Appendix C Management of Acute Asthma and Wheeze in Children >2 Years Old



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