

Arden and Greater East Midlands Commissioning Support Unit in association with
Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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NEW LINCOLNSHIRE GUIDANCE ON THE MANAGEMENT OF CHRONIC ASTHMA IN ADULTS AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

- Over the summer, PACEF have been working with the Lincolnshire Respiratory Forum to develop updated guidance on the management of two key respiratory conditions, chronic asthma and chronic obstructive pulmonary disease (COPD). This work has resulted in a genuine consensus agreement around the management of both conditions that has involved the active participation of many key opinion leaders and specialists working across United Lincolnshire Hospitals Trust and primary care.
- The objectives of the project have been to update local guidance on the management of chronic asthma in adults and COPD and to agree on the formulary status of all of the new inhalers that have been launched over the last year or more.
- The main content of this edition of the *Bulletin* is two single sheet summaries of local guidance on chronic asthma and COPD. We hope that these two documents prove easy to photocopy, laminate, put up on the consulting room wall and make readily available to all practice staff involved in the management of these patients.
- Guidance on the importance of good inhaler technique and device selection is also included. Optimum management can often be undermined by poor technique or lack of adherence to preventative therapies.

SUMMARY OF PACEF DECISIONS: SEPTEMBER 2015 UPDATE

Please note that standard first, second and third line single component inhalers are not included in this table. A clear context for their use is provided in the attached guidance on the management of chronic asthma in adults and COPD. The table is intended to record the decisions made by PACEF in relation to the newer products at PACEF meetings in July, August and September 2015.

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Ciclesonide 80 microgram and 160 microgram per actuation metered dose inhaler (<i>Alvesco</i>) (Takeda)	For persistent asthma.	AMBER for use following specialist recommendation only. Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . For place in therapy see Step 3(a) of the chronic asthma in adults guidance.
Long acting beta agonists (LABA)		
Indacaterol 150 microgram and 300 microgram capsule plus inhaler	For the maintenance treatment of COPD.	RED-RED Not approved for inclusion in the

(<i>Onbrez Breezhaler</i>) Novartis)		<i>Lincolnshire Joint Formulary.</i>
Olodaterol 2.5microgram per dose 60 dose cartridge plus <i>Respimat</i> device (<i>Striverdi Respimat</i>) (Boehringer Ingelheim)	A long acting once daily bronchodilator for the maintenance treatment of patients with chronic obstructive pulmonary disease.	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary.</i>
Long-Acting Muscarinic Antagonist (LAMA)		
Acclidinium bromide 322 microgram per dose dry powder inhaler (<i>Eklira Genuair</i>) (AstraZeneca)	For the maintenance treatment of COPD.	GREEN. Included in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see COPD guidance.
Glycopyrronium bromide 50 microgram capsule plus inhaler (<i>Seebri Breezhaler</i>) (Novartis)	For the maintenance treatment of COPD.	GREEN. Included in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see COPD guidance.
Tiotropium 18microgram capsule plus <i>Handihaler</i> (<i>Spiriva</i>) (Boehringer Ingelheim)	For the maintenance treatment of COPD.	GREEN. Included in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see COPD guidance.
Tiotropium 2.5microgram cartridge plus <i>Respimat</i> device (<i>Spiriva Respimat</i>) (Boehringer Ingelheim Ltd)	For the maintenance treatment of COPD. For use as add-on maintenance treatment of asthma in patients receiving inhaled corticosteroids and LABAs with more than one severe exacerbation in the previous year.	GREEN. Included in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see COPD guidance and Step 4 of the chronic asthma in adults guidance.
Umeclidinium dry powder inhaler (<i>Incruse Ellipta</i>) (GlaxoSmith Kline)	For the maintenance treatment of COPD.	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary.</i>
LABA/Inhaled corticosteroid (ICS) combination products		
Budesonide/ formoterol fumarate dehydrate breath actuated dry powder inhaler 160/4.5 and 320/9 (<i>DuoResp Spiromax</i>) (Teva)	Inhaled corticosteroid/long acting bronchodilator combination dry powder inhaler for the regular treatment of asthma and the symptomatic treatment of severe COPD with a history of repeated exacerbations despite regular therapy with long-acting bronchodilators.	GREEN. Approved for inclusion in the <i>Lincolnshire Joint Formulary.</i> Alternative to <i>Symbicort Turbohaler</i> at equivalent dose. For place in therapy see Step 3 of guidance on the management of chronic asthma in adults and guidance on the management of COPD.
Formoterol/beclometasone metered dose inhaler 6 microgram/ 100microgram per dose (<i>Fostair</i>) (Chiesi)	For the regular treatment of asthma where LABA/ICS combination therapy is appropriate. For the symptomatic treatment of severe COPD with a post-bronchodilator FEV1 <50% predicted and a history of exacerbations despite regular bronchodilator therapy	GREEN. Included in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see COPD guidance and Step 3(a) of the chronic asthma in adults guidance.
Formoterol/ beclometasone dry powder inhaler (<i>Fostair NEXThaler</i>) (Chiesi)	For the regular treatment of asthma in adults where LABA/ICS therapy is appropriate	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see Step 3 of guidance on the management of chronic asthma in adults.
Salmeterol xinafoate 25 microgram/ fluticasone propionate 125 or 250 microgram inhaler (<i>Sirdupla</i>) (Mylan)	For the regular treatment of asthma where long acting β_2 -agonist and inhaled corticosteroid is appropriate.	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary.</i> For place in therapy see Step 3 of guidance on the management of chronic asthma in adults. New low cost equivalent to <i>Seretide Evohaler.</i>
Vilanterol/ fluticasone furoate combination inhaler (<i>Relvar Ellipta</i>) (GlaxoSmithKline)	A combination LABA/ICS inhaler for the regular treatment of asthma and symptomatic treatment of chronic obstructive pulmonary disease with a post-bronchodilator FEV1 <70% predicted and a history of exacerbations despite regular bronchodilator therapy.	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary.</i>
LABA/Long Acting Muscarinic Antagonist (LAMA) combination products		
Formoterol fumarate dihydrate/ acclidinium bromide dry powder	For the maintenance treatment of COPD	GREEN Approved for inclusion in the

inhaler (<i>Duaklir Genuair</i>) (AstraZeneca)		<i>Lincolnshire Joint Formulary</i> . For place in therapy see COPD guidance.
Indacaterol/ glycopyrronium bromide breath activated dry powder inhaler (<i>Ultibro Breezhaler</i>) (Novartis)	For the maintenance treatment of COPD	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . For place in therapy see COPD guidance.
Olodaterol/ tiotropium bromide monohydrate inhaler (<i>Spiolto Respimat</i>) (Boehringer Ingelheim Ltd)	For the maintenance treatment for COPD	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . For place in therapy see COPD guidance.
Vilanterol/ umeclidinium dry powder inhaler (<i>Anoro Ellipta</i>) (GlaxoSmithKline)	For the maintenance treatment of COPD	RED-RED Not approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .

This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Back issues of the *PACE Bulletin* and other PACEF publications are available through the PACEF website (<http://lincolnshire-pacef.nhs.uk>); follow the commissioning link to PACEF. Electronic copies of the *PACE Bulletin* are circulated to a wide readership via email. If you are not currently on our distribution list and wish to receive regular copies of PACEF publications please contact Sandra France on sandra.france@gemcsu.nhs.uk.

Google searching can be a quick and effective way of finding back numbers of the *PACE Bulletin* relevant to a specific topic of interest. Searchers are advised to use the official version of the *Bulletin* available from the PACEF website rather than depend on a potentially unreliable draft or variant found through Google or an alternative search engine.

The *Lincolnshire Joint Formulary* is available on line and is fully searchable; it can be accessed at www.lincolnshirejointformulary.nhs.uk

RED-RED: This signifies that a product is **not recommended** for prescribing in **either** primary or secondary care. All new products are classified as RED-RED pending assessment by PACEF.
RED: This signifies that a product has been approved for use within secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary care.
AMBER: This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; PACEF are working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care**.

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DEVICE is paramount.
Good inhaler technique is essential
A device the patient cannot use is USELESS

Inhaled corticosteroids (ICS) are the mainstay of treatment.
 Smoking will reduce their effect.
 Remember to promote good oral hygiene to reduce the chance of oral candidiasis.

Long acting beta agonists (LABA) should not be used without an ICS.
 Combinations are non-inferior to separates.
 Combinations can improve concordance and reduce prescription charges for patients.

Leukotriene receptor antagonists (LTRA) are a useful add-on to ICS and LABA. Montelukast is licensed for the prophylaxis of asthma and symptomatic relief of seasonal allergic rhinitis; zafirlukast for the treatment of asthma.

Severe asthma phenotypes:


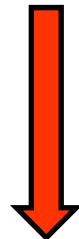
(1) *Allergic asthma:*
 IgE plays an important role in worsening this severe phenotype of asthma. Anti IgE therapy can be considered. Secondary care referral is needed.

(2) *Non-atopic, inflammation predominant asthma:*
 Associated with increased eosinophils and small airway inflammation leading to fixed airflow limitation. Frequently have rhinosinusitis, nasal polyps and aspirin sensitivity.
 Check for asymptomatic nasal polyps. Consider ultrafine particles

(3) *Obesity:*
 Increasingly common phenotype. Possibly due to: mechanical factors, pro-inflammatory effects of adipose tissue, co-morbidities (e.g. gastro-oesophageal reflux, obstructive sleep apnoea).
 The only treatment is WEIGHT LOSS.

Stepwise Management of Chronic Asthma in Adults

 Review and reduce (step down)	STEP 1 <i>Mild intermittent asthma</i>	Inhaled short-acting beta agonist (SABA) as required. Move to ICS if needed 3 or more times weekly. 1. Salbutamol <i>Easi-Breathe</i> or Salbutamol MDI (with or without spacer) or Salbutamol <i>Easyhaler</i> . 2. Terbutaline <i>Turbohaler</i> (restricted). Bambuterol tablet (only for those who cannot use inhalers at all).
	STEP 2 <i>Regular Preventer therapy</i>	Add ICS 400-800 microgram daily (Beclometasone dipropionate (BDP) or equivalent). Dose according to severity. 1. Beclometasone <i>Qvar Easi-Breathe</i> or Beclometasone MDI (<i>Clenil Modulite</i>) (with or without spacer). Prescribe by brand. <i>Qvar</i> and <i>Clenil</i> brands of BDP inhalers are not dose equivalent. 1. Beclometasone or budesonide <i>Easyhaler</i> 2. Budesonide <i>Turbohaler</i> 2. Fluticasone <i>Accuhaler</i> or Fluticasone MDI (+ or – spacer)
	STEP 3 (a) <i>Initial add-on therapy</i>	Add LABA 1. Formoterol <i>Easyhaler</i> or MDI (<i>Atimos Modulite</i>) (with or without spacer) 2. Salmeterol <i>Accuhaler</i> or MDI (with or without spacer) or combinations: 1. Beclometasone/formoterol (<i>Fostair</i>) MDI (with or without spacer). 1. Budesonide/formoterol (<i>Symbicort Turbohaler/DuoResp Spiromax</i>). 2. Fluticasone/salmeterol (<i>Seretide Accuhaler</i> or <i>Evohaler</i> or <i>Sirdupla</i>) (with or without spacer) – only use if failed to respond to beclometasone or budesonide. • Ciclesonide MDI (<i>Alvesco</i>) (following specialist review only). Assess control: good response – continue; no response – stop; some response – move to 3b
	STEP 3 (b) <i>Initial add-on therapy</i>	Initially increase ICS to 800 microgram daily. Assess control: good response – continue; inadequate response - institute trial of other therapies. <ul style="list-style-type: none"> • LTRA: Montelukast (or zafirlukast following specialist review). • Theophyllines: <i>Uniphyllin, Phyllocontin</i>. Restricted theophyllines: <i>Nuelin, Slophyllin</i> • Oral LABA: Bambuterol
	STEP 4 <i>Persistent poor control</i>	Consider trials of: <ul style="list-style-type: none"> • Tiotropium <i>Respimat</i> • Increase inhaled steroid to 2000 micrograms per day (BDP or equivalent) • Addition of fourth drug (see 3b)
 Review and increase (step up)	STEP 5 <i>Continuous or frequent use of oral steroids</i>	Refer patient for specialist care <ul style="list-style-type: none"> • Maintain inhaled steroid to 2000 micrograms per day (BDP or equivalent) • Use daily steroid tablet in lowest dose providing adequate control • Consider other treatments to minimize the use of steroid tablets: <ul style="list-style-type: none"> • Methotrexate, gold, ciclosporin (specialist only) • Omalizumab (specialist only)
	<p>Please note: Uncontrolled asthma is waking at night ONCE A WEEK with asthma symptoms or needing to use a reliever inhaler 3 TIMES A WEEK or more. These patients need a review and MUST be on an inhaled steroid (at least).</p>	

<p>DEVICE is paramount: Good inhaler technique is essential. A device the patient cannot use is USELESS</p>	<p>Asthma/COPD overlap syndrome (ACOS)</p>	<p>Stepwise Management of COPD diagnosed with spirometric staging</p>			
<p>Check inhaler technique at every review</p>	<p>Follow asthma pathway</p>	<p>Start with short-acting beta agonist (SABA) or SAMA:</p> <ol style="list-style-type: none"> Salbutamol <i>Easi-Breathe / Easyhaler</i> Salbutamol or ipratropium MDI (with or without spacer) <ul style="list-style-type: none"> Bambuterol tablet (only for those who cannot use inhalers at all) 			
<p>Smoking cessation is one of the most important components of therapy. All patients continuing to smoke should be encouraged to stop. Tel Phoenix on: 0800 8401533.</p>	<p>Where possible do not commence more than one medication at the same time as this will make it difficult to assess the benefit (or lack of benefit) of individual drugs.</p>	<p>add</p>			
<p>Pulmonary rehabilitation should be made available to all appropriate patients.</p>		<p>Long acting beta agonist (LABA) or LAMA</p> <table border="0"> <tr> <td> <ol style="list-style-type: none"> Formoterol <i>Easyhaler</i> or <i>Atmos</i> MDI (with without spacer) Salmeterol <i>Accuhaler</i> (MDI not licenced) </td> <td> <ol style="list-style-type: none"> Tiotropium (<i>Spiriva Handihaler</i> or <i>Respimat</i>) Acclidinium bromide (<i>Eklira Genuair</i>) Glycopyrronium bromide (<i>Seebri Breezhaler</i>) </td> </tr> </table>		<ol style="list-style-type: none"> Formoterol <i>Easyhaler</i> or <i>Atmos</i> MDI (with without spacer) Salmeterol <i>Accuhaler</i> (MDI not licenced) 	<ol style="list-style-type: none"> Tiotropium (<i>Spiriva Handihaler</i> or <i>Respimat</i>) Acclidinium bromide (<i>Eklira Genuair</i>) Glycopyrronium bromide (<i>Seebri Breezhaler</i>)
<ol style="list-style-type: none"> Formoterol <i>Easyhaler</i> or <i>Atmos</i> MDI (with without spacer) Salmeterol <i>Accuhaler</i> (MDI not licenced) 		<ol style="list-style-type: none"> Tiotropium (<i>Spiriva Handihaler</i> or <i>Respimat</i>) Acclidinium bromide (<i>Eklira Genuair</i>) Glycopyrronium bromide (<i>Seebri Breezhaler</i>) 			
<p>Remember that short-acting muscarinic antagonists (SAMA) and long-acting muscarinic antagonists (LAMA) can cause dry, tenacious phlegm; consider stopping for a trial period if this is a problem.</p>		<p>FEV1 ≤50% - Move to LABA and LAMA as above or</p>			
<p>Carbocisteine can be trialled if phlegm remains problematic. Don't forget to reduce to maintenance dose after the trial period</p>		<p>LABA/LAMA combination: Where possible stick to same device or LAMA</p> <ol style="list-style-type: none"> Tiotropium/olodaterol (<i>Spiolto Respimat</i>) Acclidinium/formoterol (<i>Duaklir Genuair</i>) Glycopyrronium/indacaterol (<i>Ultibro Breezhaler</i>) 			
<p>Self-Management Plans and patient education have been shown to reduce admissions.</p>	<p>Continuing breathlessness without exacerbations</p>	<p>Frequent exacerbator - >2 per year (one exacerbation pa does not = frequent, especially at diagnosis)</p> 			
<p>Consider the patient's risk of pneumonia. Do not commence high dose ICS in those at higher risk unless exacerbations are a significant problem.</p>		<p>ICS/LABA and LAMA – choose LAMA from above and add:</p> <ol style="list-style-type: none"> Beclometasone/formoterol (<i>Fostair</i>) MDI (with or without spacer) Budesonide/formoterol (<i>Symbicort Turbohaler 400/12/ DuoResp Spiromax 320/9</i>) Fluticasone/salmeterol (<i>Seretide Accuhaler 50/500</i>) 			
<p>Do not stop ICS abruptly, wean off slowly.</p>	<p>If patient continues to have uncontrolled breathlessness or exacerbations after trial of the above: Check SpO2, consider theophyllines, review diagnosis, consider referral to secondary care DO NOT recommend nebulised therapy - refer for opinion</p>				

GUIDANCE ON INHALER DEVICE SELECTION FOR ADULTS

The inhaled route is the first line administration method in the management of asthma and COPD. It is well documented that patients can have problems adopting the correct inhalation technique and will receive inadequate doses of medication as a result. This can lead to poor disease control and unnecessarily increased healthcare costs (1). It has been shown that healthcare expenditure for an uncontrolled patient is more than double that of a controlled patient (2). Incorrect inhaler use has been found in 4 times as many patients with uncontrolled asthma (3). Cost of inhalers alone should not determine prescribing recommendations. (4).

The following is an indication of the potential problems that can be encountered when reviewing inhaler technique with suggested solutions:

Inspiratory flow and time

The patient's inspiratory flow rate affects the velocity of the airborne particles from the inhaler. This in turn, affects the probability of impaction in the oropharynx and larynx. **When using a pressurized metered dose inhaler (pMDI)(with or without spacer) or breath activated pMDI, to minimise upper airway deposition and enhance drug delivery to the lungs, the inhaler user must inhale slowly (~30L/min) for 4-5 seconds (8). With dry powder inhalers, the patient has to inhale as deeply and as hard as they can (≥30L/min) to overcome the internal resistance to flow and generate the aerosol for inhalation (8).** Breath holding after inhalation is important for increasing deposition in the peripheral airways (8). A breath hold of at least 5 seconds is recommended (3). Patients with a short inspiratory time (1-3 seconds) and/or inability to breathe hold, may benefit from changing to a pMDI with a spacer, using tidal breathing.

Lack of patient tuition

Patients cannot be expected to use an inhaler properly without training. Inhalers should only be prescribed after correct training and demonstration by the patient that they can use the selected inhaler effectively (5). A low proportion of patients receive education in inhaler use and an even lower number have their technique reviewed over time (1). Regular review of inhalation technique is recommended (5) as only approximately half of patients who have good inhaler technique initially, maintain this correct technique over time (1).

Poor healthcare professional skill in inhaler technique

Only 15-69% of healthcare professionals, across all disciplines, can demonstrate correct inhaler use (1). It has been suggested that a system of validation of training ability and inhalation assessment be developed (1). In the interim, it is the healthcare professional's responsibility to ensure that they are sufficiently skilled to undertake inhaler training and prescribing.

Poor co-ordination

When using a pressurised metered dose inhaler (pMDI), poor co-ordination between actuation and inhalation is one of the most common mistakes and has been shown to reduce lung deposition to 7.2% (6). One study showed that over 60% of patients were unable to use their

pMDI correctly after being shown how on 3 separate occasions (4). The use of a spacer has been shown to be the least preferred option by patients, with the *Easibreathe* being the most popular device of 7 devices in one study (7).

Patients who need assistance

If a patient is unable to prime their inhaler prior to use, it is acceptable for a carer to prime all breath activated inhalers for the patient, including dry powder inhalers (DPI). It is not acceptable to actuate a pMDI for a patient unless it is used in conjunction with a spacer. Patients who have difficulty actuating inhalers may be able to manage with the addition of an adjunct (e.g. *Haleraid* 120 or 200 for Glaxo Smith Kline pMDIs or *Turbohaler* aid). Patients who need complete assistance with inhalers **must have** a pMDI and spacer. The nose is a more effective filter than the mouth and, as a result, the mouth is the preferred route for aerosol delivery to the lungs (8). Spacers with face masks should **not** be used for adults unless the patient is incapable of inhaling through the mouth.

Oropharyngeal side-effects

Oropharyngeal side-effects such as thrush or hoarse voice are not uncommon with inhaled corticosteroid (ICS) therapy. Oral hygiene, including mouth rinsing should be recommended to all patients using ICS therapy. If symptoms persist, a change to ultrafine particle ICS will lower oropharyngeal deposition (8) and may decrease symptoms. Use of a pMDI and spacer will also decrease oropharyngeal deposition and symptoms.

Poor adherence

Patients who are reluctant to use their ICS have been shown to benefit from single inhaler therapy (e.g. *Symbicort SMART* or *Fostair MART*).

Patients without intact executive function

It has been shown that patients with Mini Mental State Examination (MMSE) <23, an AMT <7 or EXIT25 (for executive function) <14 are unlikely to be able to use an inhaler (9). Furthermore, Board and Allen (10) have shown that patients who were unable to perform the pentagon copying test from the MMSE, are unlikely to be able to use a self-administered inhaler. Such patients should have assistance to use a pMDI and spacer or be prescribed oral therapy.



	<i>Easibreathe</i>	pMDI and spacer	<i>Respimat</i>	pMDI	<i>Easyhaler</i>	<i>Turbohaler</i>	<i>Accuhaler</i>	<i>Genuair</i>	<i>Handihaler/Breezhaler</i>	Oral Medication
Poor co-ordination	✓	✓	✓		✓	✓	✓	✓	✓	
Low inspiratory time		✓								
Can use if primed for them	✓	✓			✓	✓	✓	✓	✓	
Oropharyngeal side effects	May improve with ultrafine particles (<i>Qvar</i>)	✓	Dry mouth with LAMA	May improve with ultrafine particles (<i>Qvar</i> or <i>Fostair</i>)				Dry mouth with LAMA	Dry mouth with LAMA	
Unable to administer unaided		✓								
Poor adherence to ICS		<i>Fostair MART</i>	N/A	<i>Fostair MART</i>		<i>Symbicort SMART</i>		N/A	N/A	
Difficulty priming device		Add <i>Haleraid</i> (GSK only)		Add <i>Haleraid</i> (GSK only)		Add <i>Turbohaler aid</i>				
Dementia or MMSE <24*		✓ with assistance								✓

*see "patients without intact executive function"

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