

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 *PACE* Shorts

Summary of PACEF decisions from June 2016

For further details see *PACE Bulletin* Volume 10; Number 12 (August 2016)

SUMMARY OF PACEF DECISIONS: JUNE 2016 UPDATE

Device, Dressing or Drug	Indication(s)	Traffic Light and <i>Joint Formulary</i> Status
Alogliptin 6.25mg, 12.5mg and 25mg tablets (Vipidia)	For the management of type 2 diabetes mellitus in adults to improve glycaemic control in combination with other glucose lowering therapies, including insulin when these together with diet and exercise do not provide adequate glycaemic control.	GREEN First line DPP-4 inhibitor of choice. Included in the Lincolnshire Joint Formulary.
Alogliptin/metformin 12.5mg/1g tablets (Vipdomet)	For the management of type 2 diabetes mellitus in adults: <ul style="list-style-type: none"> - as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of alogliptin and metformin. - in combination with pioglitazone (i.e. triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and pioglitazone. - in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. 	GREEN Alogliptin is the first line DPP-4 inhibitor of choice. Included in the Lincolnshire Joint Formulary.
Linagliptin 5mg tablets (Trajenta) (Boehringer Ingelheim)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; as monotherapy when metformin is inappropriate; with metformin when metformin alone is inadequate; with metformin and a	GREEN Second line DPP-4 inhibitor approved for use in patients with severe renal or hepatic impairment. Included in the Lincolnshire Joint Formulary.

	sulfonylurea when dual therapy is inadequate ; or with insulin when insulin, with or without metformin , is inadequate.	
Linagliptin/metformin 2.5mg/850mg and 2.5mg/1g (Jentadueto) (Boehringer Ingelheim)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; when metformin alone is inadequate; in patients who are currently receiving the combination as separate tablets; with a sulfonylurea when a sulfonylurea plus metformin is inadequate; or with insulin when insulin plus metformin is inadequate.	GREEN Linagliptin is a second line DPP-4 inhibitor approved for use in patients with severe renal or hepatic impairment. Included in the Lincolnshire Joint Formulary.
Saxagliptin 2.5mg and 5mg tablets (Onglyza) (AstraZeneca)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; as monotherapy when metformin is inappropriate; with metformin or a glitazone when either agent alone is inadequate; with a sulfonylurea when metformin is inappropriate and a sulfonylurea alone is inadequate; with metformin and a sulfonylurea when dual therapy is inadequate or with insulin when insulin, with or without metformin, is inadequate.	RED-RED In view of continuing cardiovascular concerns and declining use, removed from the Lincolnshire Joint Formulary.
Saxagliptin/metformin 2.5mg/850mg and 2.5mg/1g tablets (Komboglyza) (AstraZeneca)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; when metformin alone is inadequate; in patients who are currently receiving the combination as separate tablets; with a sulfonylurea when a sulfonylurea plus metformin is inadequate; or with insulin when insulin plus metformin is inadequate.	RED-RED In view of continuing cardiovascular concerns and declining use, not approved for use on the Lincolnshire Joint Formulary.
Sitagliptin 100mg tablets (Januvia) (MSD)	Treatment of type 2 diabetes as monotherapy when metformin is inappropriate due to contraindications or intolerance, dual therapy in combination with metformin, sulfonylurea or glitazone or triple oral therapy in combination with a sulfonylurea plus metformin or glitazone plus metformin or with insulin with or without metformin.	GREEN Second line DPP-4 inhibitor of choice. Included in the Lincolnshire Joint Formulary.
Sitagliptin 50mg/metformin 1g (Janumet) (MSD)	Treatment of type 2 diabetes as monotherapy when metformin is inappropriate due to contraindications or intolerance, dual therapy in combination with metformin, sulfonylurea or glitazone or triple oral therapy in combination with a sulphonylurea plus metformin or glitazone plus metformin or with insulin with or without metformin.	GREEN Second line DPP-4 inhibitor/ metformin combination product of choice. Included in the Lincolnshire Joint Formulary.
Vildagliptin 50mg tablets (Galvus) (Novartis)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; as monotherapy when metformin is inappropriate; with metformin or a glitazone when either agent alone is inadequate; with a sulfonylurea when metformin is inappropriate and a sulfonylurea alone is inadequate; with metformin and a sulfonylurea when dual therapy is	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary

	inadequate or with insulin when insulin, with or without metformin, is inadequate.	
Vildagliptin/metformin 50mg/850mg and 50mg/1g tablets (Eucreas) (Novartis)	For the treatment of type 2 diabetes inadequately controlled by diet and exercise; when metformin alone is inadequate; in patients who are currently receiving the combination as separate tablets; with a sulfonylurea when a sulfonylurea plus metformin is inadequate; or with insulin when insulin plus metformin is inadequate.	RED-RED Not approved for inclusion in the Lincolnshire Joint Formulary

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**.

What's new this month?

- Existing patients on alternative DPP-4 inhibitors should be reviewed and considered for a therapeutic switch to alogliptin.
- The American Food and Drug Administration (FDA) recently published a safety review of saxagliptin and alogliptin that identified a possible increased risk of hospitalisation for heart failure in patients taking these medicines who already have heart or kidney disease. As a result of this, additional warnings and precautions have been added to the labels of both these products in the USA. PACEF have reviewed the trial evidence linking both drugs to increased hospitalisation due to heart failure and acknowledge that there is a small increased risk, particularly in those with pre-existing heart or kidney disease. At this stage, it is too early to tell whether this is potentially a risk with all DPP-4 inhibitors or whether this is related solely to specific agents.
- When initiating new patients on alogliptin or switching existing patients to alogliptin, prescribers should be mindful of existing SPC advice which is to avoid in severe renal impairment and exercise caution in those with pre-existing heart failure. All patients taking alogliptin or saxagliptin (or any other DPP-4 inhibitor) should be advised to contact their healthcare professional right away if they develop the signs and symptoms of heart failure such as unusual shortness of breath during daily activities, breathing difficulties when lying down, tiredness, weakness, fatigue or weight gain with swelling of the ankles, feet, legs or stomach. The MHRA have not yet published on this issue, but may choose to do so imminently. Local guidance and switch protocols will be amended in accordance with any subsequent advice from the MHRA.

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 *PACE Shorts* 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@ardengemcsu.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

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