Abstract

Plymouth Hospital NHS Trust (PHNT) has risen to the Quality, Innovation, Productivity, and Prevention (QIPP) challenge, by piloting a prostate cancer homecare service fully funded and project managed by Janssen. The purpose of the pilot was to enable the current service to be more efficient, whilst offering patients a high quality homecare service for abiraterone (Zytiga®), Janssen’s oral prostate cancer therapy. NHS uro-oncology services continue to be challenged with the emergence of new treatments for metastatic castration-resistant prostate cancer (mCRPC), with a growing requirement for increased monitoring for these patients. Providing patient care in the home setting is seen as a potential solution to overcoming these capacity issues and aligns with the Trust’s overarching quality ambition to improve patient and staff experience, and use its resources more efficiently.

A market research study was conducted by GfK’s UK Health Industry team, 12 months on from the pilot initiation to identify to what extent the homecare pilot had improved the patients’ and caregivers’ experience when receiving abiraterone, an oral anticancer therapy to treat their mCRPC either pre or post docetaxel chemotherapy in the home setting.

The results have demonstrated patient good adherence to treatment, positive patient satisfaction for the service provided, and reduced pressure on existing hospital capacity, allowing the centre to accommodate and manage new and more complex patients. Part of the success of this pilot was due to the communication matrix between the homecare company and lead consultant, which was very tightly controlled.

Background

There are up to 200,000 people in England who receive a homecare service, which has helped to improve their lives whilst they suffer from chronic or stable conditions that require regular treatment and monitoring. Many of the chemotherapy treatments for cancer can be safely delivered away from major cancer centres.
Outline of the Homecare Service Model

Oral prostate cancer treatment offers an opportunity to manage a cohort of prostate cancer patients in their home thus freeing up hospital capacity and consultant time for more complex patients, whilst also improving the patient experience.

Patient selection and referral to homecare service through lead clinician

Upon registration PHNTR completes a homecare service patient referral form and send a clinically screened prescription to homecare service*

Schedules visits to the patients’ homes and complete Patient Information Form

Return bloods to Plymouth Hospital NHS Trust phlebotomy services

CNS/oncology nurse from homecare company takes patient's blood; conducts clinical assessment, provides patient support and counselling**

* Prescriptions need to be completed by the lead clinician and will only be valid if bearing the Trust's “Received in Pharmacy” and date stamp.
** refer to full case study for homecare nurse full monitoring details

Costing out the service

The cost of a homecare service can vary between clinical areas, as there may be service frameworks and agreements already in place with homecare companies. There are often locally agreed procurement arrangements established through local commissioning and local rates and pricing agreements would have to be applied. There may also be cost variance between the homecare companies. The figures below are therefore only indicative costs.

Month 1 (£345)
- Nurse visit x2 (£345)
- Dispensing and delivery of medication (£35)
- Registration call (£35)
- Pharmacy call (£15)
- Reminder call (£5)

Month 2 & 3 (£295 per month)
- Nurse visit x2 (£345)
- Dispensing and delivery of medication (£35)
- Reminder call (£5)

Month 4 onwards (£175)
- Nurse visit x2 (£120)
- Dispensing and delivery of medication (£35)
- Reminder call (£5)

Homecare pilot costs - per patient per year
- 12 month homecare service costs £2,510
- These costs could be offset through potential VAT savings achieved by community dispensing or home delivery of abiraterone

Benefits and Research Results

Benefits to patients
✓ Increases patient choice
✓ Supports the message that their treatment is important
✓ Lessens the burden of treatment
✓ Adds additional channels of communication

Benefits to significant others
✓ Feel reassured the treatment being administered is high quality
✓ Allows them to feel more engaged in the treatment process in general
Benefits to nurses
✓ Allows a more holistic view of the patient
✓ Gives the opportunity to see the reality of patients’ lives

Benefits to the consultant
✓ Creates extra capacity for the lead consultant to focus on other areas of their role

Consultant time is significantly reduced when patients are managed through homecare without compromising patient care or experience
✓ Increases physician’s personal satisfaction with the role they perform
✓ Increases the number of touch points the patient experiences during their care

Benefits to the overall healthcare system
✓ No negative effects on the hospital’s financial position as the service can be fully sustainable within the present budget
✓ Lessens the pressure on phlebotomy services
✓ More frequent interactions allow for earlier interventions

Under the home-based setting:
• Consultant oncologist would call patient at least once every eight weeks for 10 minutes (telephone consultation)
• Saves patients and their families up to 8 return trips to clinic over 12 months and the costs associated with that (e.g. fuel, parking, time)
• Frees up capacity in clinic for other patients requiring a face to face consultation

Although these patients are managed in the home setting it is essential that the lead consultant retains the responsibility for overall patient care across the whole pathway, provides care when a patient is receiving treatment in a different setting/service and retains overall responsibility for the management of side effects and complications.

Conclusion

The Government puts patients at the heart of the NHS and everything that it does and is seeking to empower and liberate clinicians to innovate with freedom to improve health services. Patients do not hold back in expressing the benefits they experience from homecare medicine. At the same time, homecare medicine is enabling NHS clinicians and managers to redesign patient care pathways in ways that are providing the NHS with opportunities to increase the value for money that it provides taxpayers with, in line with Government policies. This homecare-based service supports the Government agenda to offer care closer to home and in doing so improve the patient’s experience of care.

The approach of using a homecare supply arrangement for selected oral agents is a good example of how three of the QIPP requirements have been met.

• Quality: patient and caregiver waiting times have reduced

Table illustrates that patients in pilot spend less time waiting and travelling to consultations. In addition, the reduced contact time with HCPs did not result in less satisfaction with their HCP contacts.

• Innovation: in respect of new ways of working and providing a gold standard service in the NHS; and
• Productivity: given that it facilitates faster patient through and provides the potential to treat more patients using the clinic and homecare setting. With the homecare setting the hospital saves the VAT.

Key Learning Points
• It is important to have a clear understanding of the commissioning arrangements before the service is implemented. Every locality will have commissioning nuances and any joint working with primary care should be mapped out, addressed and agreed before initiating such a project.
• To improve the experience of both patients and care givers receiving treatment for mCRPC, an out of hospital service should become the standard process for the delivery and management of oral anticancer treatment across NHS Trusts.
• Due to the success of the pilot, a business case for care closer to home has been submitted and is under review.

Written by Dr Sarah Pascoe Clinical Oncologist; CNS and Urological Cancers.
ZYTIQA® ▼ 250 mg Tablets PRESCRIBING INFORMATION ACTIVE INGREDIENT(S): Abiraterone acetate Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S):
Taken with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. The treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.

DOSEAGE & ADMINISTRATION:
Adults: 1000 mg (4 tablets) single daily dose. Not with food as this increases the systemic exposure (take dose at least two hours after eating; no food for at least one hour post-dose). Swallow whole with water. Take with recommended dose of prednisone or prednisolone of 10 mg daily. Medical castration with LHRH analogue should be continued during treatment with Zytiga, consider maintaining potassium level at ≥4.0 mM. Patients who develop Grade ≥3 toxicities (hypertension, hypokalaemia, oedema and other non-mineralocorticoid toxicities) stop treatment and start appropriate medical management. Do not restart Zytiga until symptoms of the toxicity have resolved to Grade 1 or baseline. Renal impairment: No dose adjustment, however no experience in patients with prostate cancer and severe renal impairment; caution advised. Hepatotoxicity: If hepatotoxicity develops (ALT or AST >5x upper limit of normal - ULN), stop treatment immediately until liver function returns to baseline; restart Zytiga at 500 mg (2 tablets) once daily and monitor serum transaminases at least every 2 weeks for 3 months and monthly thereafter (see Special warnings & precautions). If hepatotoxicity recurs on reduced dose, stop treatment. If severe hepatotoxicity develops (ALT or AST 20xULN), discontinue Zytiga and do not restart. Hepatic impairment: Mild (Child-Pugh class A) - no dose adjustment required. Moderate (Child-Pugh class B) - approximately 4x increased systemic exposure after single oral doses of 1,000 mg. Moderate/Severe (Child-Pugh class C or B) - no clinical data for multiple doses. Use with caution in moderate impairment, benefit should clearly outweigh risk.

CONTRAINDICATIONS:
Pregnancy or potential to be pregnant. Hypersensitivity to active substance or any excipients. Severe hepatic impairment (Child-Pugh Class C).

SPECIAL WARNINGS & PRECAUTIONS:
Zytiga may cause hypertension, hypokalaemia and fluid retention due to increased mineralocorticoid levels. Cardiovascular: Caution in patients with history of cardiovascular disease. In patients with a significant risk for congestive heart failure (history of cardiac failure, uncontrolled hypertension, ischaemic heart disease) consider an assessment of cardiac function before treating (echocardiogram). Safety not established in patients with left ventricular ejection fraction <50% or NYHA Class II to IV (pre-chemotherapy) and III or IV (post-chemotherapy) heart failure. Before treatment cardiac failure should be treated and cardiac function optimised. Correct and control Hypertension, hypokalaemia and fluid retention pre-treatment. Caution in patients whose medical conditions might be compromised by hypertension, hypokalaemia or fluid retention e.g. heart failure, severe or unstable angina pectoris, recent myocardial infarction or ventricular arrhythmia, severe renal impairment. Monitor blood pressure, serum potassium and fluid retention and other signs and symptoms of congestive heart failure before treatment, then every two weeks for 3 months, and monthly thereafter. Consider discontinuation if there is a clinically significant decrease in cardiac function. Hepatotoxicity & Hepatic impairment: Measure serum transaminases pre-treatment and every two weeks for first three months, then monthly. If symptoms/signs suggest hepatotoxicity, immediately measure serum transaminases. If ALT or AST > 5x ULN, stop treatment and monitor liver function. Restart treatment after liver function returns to baseline; use reduced dose (see dosage and administration). No clinical data in patients with active or symptomatic viral hepatitis. Corticosteroid withdrawal: Monitor for adrenocortical insufficiency if prednisone or prednisolone is withdrawn. Monitor for mineralocorticoid excess if Zytiga plus glucocorticoid. Prior use of ketoconazole: Lower response rates may occur in patients previously treated with ketoconazole for prostate cancer. Hyperglycaemia: Use of glucocorticoids could increase hyperglycaemia, measure blood sugar frequently in patients with diabetes. Use with chemotherapy: Safety and efficacy of concomitant use of Zytiga with cytotoxic chemotherapy not established. Intolerance to excipients: Not to be taken by patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Take sodium content into account for those on controlled sodium diet. Potential risks: Anaemia and sexual dysfunction may occur in men with metastatic castration resistant prostate cancer including those taking Zytiga. Skeletal Muscle Effects: Cases of myopathy reported. Some patients had rhabdomyolysis with renal failure. Caution is recommended in patients concomitantly treated with drugs known to be associated with myopathy/rhabdomyolysis.

SIDE EFFECTS:
Very common: urinary tract infection, hypokalaemia, hypertension, diarrhoea, peripheral oedema. Common: sepsis, hypertriglyceridaemia, cardiac failure (including congestive heart failure, left ventricular dysfunction and decreased ejection fraction), angina pectoris, arrhythmia, atrial fibrillation, tachycardia, dyspepsia, increased alanine aminotransferase, increased aspartate aminotransferase, rash, haematuria, fractures (includes all fractures with the exception of pathological fracture).
Other side effects: adrenal insufficiency, myopathy, rhabdomyolysis. Refer to SmPC for other side effects.

FERTILITY/PREGNANCY/LACTATION:
Not for use in women. Not known whether abiraterone or its metabolites are present in semen. A condom is required if the patient is engaged in sexual activity with a pregnant woman. If the patient is engaged in sexual activity with a woman of childbearing potential, a condom is required along with another effective contraceptive method. Studies have shown that abiraterone affected fertility in male and female rats, but these effects were fully reversible.

INTERACTIONS:
Cautions with drugs activated by or metabolised by CYP2D6 particularly when there is a narrow therapeutic index e.g. metoprolol, propranolol, desipramine, venlafaxine, haloperidol, risperidone, propafenone, flecainide, codeine, oxcodone and tramadol. Avoid strong inducers of CYP3A4 (e.g. phenytoin, carbamazepine, rifampicin, rifabutin, rifapentine, phenobarbital, St John's wort). Zytiga is a CYP2C8 inhibitor (in vitro data). Examples of medicinal products metabolised by CYP2C8 incl paclizaxel, repaglinide. No clinical data are available on the use of Zytiga with CYP2C8 substrates. May increase concentrations of drugs eliminated by OATPIB1. Food (see Dosage & Administration).

Refer to SmPC for full details of interactions.

LEGAL CATEGORY: POM

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBERS & BASIC NHS COSTS EU/1/11/714/001; 120 tablets: £2930.

MARKETING AUTHORISATION HOLDER: JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. © Janssen-Cilag Ltd 2014

Adverse events should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse reactions related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447.

Prescribing information last revised: May 2014

PHGB/ZY1/0514/0026: Date of Preparation: July 2014