**SUPPLEMENTARY MATERIAL**

**EU4 Severe Chronic Low Back Pain Patient Journey Research Methodology**

**Sample**

* Qualitative (interview based) market research was conducted in four European markets: United Kingdom (UK), Germany (DE), Italy (IT), Spain (SP)
* The sample was comprised from general practitioners (GPs) (n=40) and severe chronic lower back pain patients (n=20)
* The sample can be broken down as follows:

|  |  |
| --- | --- |
| GPs | Patients |
| UK: n=10 respondents | UK: n=5 respondents |
| DE: n=10 respondents | DE: n=5 respondents |
| IT: n=10 respondents | IT: n=5 respondents |
| SP: n=10 respondents | SP: n=5 respondents |

**Recruitment**

* GPs were recruited through a panel approach
* Severe chronic lower back pain patients were recruited through referrals from GPs
* A summary of the screening criteria can be found below:

|  |  |
| --- | --- |
| GPs | Patients |
| ≥3 years working as GP | Must be ≥18 years, but ≤75 years |
| ≥70% of time spent managing patients |
| Personally responsible for managing and treating patients with severe chronic lower back pain | Must have been diagnosed with severe chronic lower back pain for >12 months |
| Must see >5 severe chronic lower back pain in a month |
| Must be personally responsible for initiating opioid treatments in patients with severe chronic lower back pain | Must be on a strong opioid or tramadol |
| Must be Palexia prescribers |

* The detailed screeners can be found in Appendix 1

**Homework tasks**

* GPs completed anonymised Patient Record Forms (PRFs) in advance of their interview, thus allowing interviews to be anchored in real clinical cases
* The PRFs were designed to understand the following, for two patient types – a patient currently receiving a strong analgesic / opioid, and a patient not currently receiving a strong analgesic / opioid
  + ***Clinical characteristics***: time since diagnosis, number of GP visits since diagnosis, treatments received
  + ***Non-clinical characteristics***: age, home life status, working status, comorbidities, current impact on severe chronic lower back pain on life
  + ***Treatment goals***
* The detailed homework task can be found in Appendix 2
* There was no homework associated with the patient interviews

**Research methods**

* Within each market 1 Central Location (CL) was held and the research method can be broken as follows:

|  |  |
| --- | --- |
| GPs | Patients |
| 2 x 60 mins In-Depth 1 on 1 Interviews (IDIs) | 3 x 60 mins In-Depth 1 on 1 Interviews (IDIs) |
| 1 x 120 mins creative mini group (n=4) |

* The remainder of the interviews were conducted as Telephone-Depth Interviews (TDIs):

|  |  |
| --- | --- |
| GPs | Patients |
| 4 x 60 mins 1 on 1 Telephone-Depth Interviews (TDIs) | 2 x 60 mins 1 on 1 Telephone-Depth Interviews (TDIs) |

* The detailed discussion guides used can be found in Appendix 3

**Appendix**

**Appendix 1**

**Appendix 1.1 – GP screener**

**Demographics**

Prior to the market research taking place we would like to ask you a few questions to determine whether the project would be suitable for you.

|  |  |  |
| --- | --- | --- |
| **D1** | **location** | |
| United Kingdom | | 1 |
| Spain | | 2 |
| Italy | | 3 |
| Germany | | 4 |
| Other | | 99 ***>> Close*** |

***>> n=5 patients per market***

|  |  |  |
| --- | --- | --- |
| **D2** | **Respondent type** | |
| Primary care physician / General practitioner | | 1 |
| Other | | ***2>> Close*** |

|  |  |  |
| --- | --- | --- |
| **D3** | **years in current role** | |
| Number of years working as a GP or specialist? | | |
| <3 years | | 1 ***>>Close*** |
| ≥3 years | | 2 |

|  |  |  |
| --- | --- | --- |
| **D4** | **time spent managing patients** | |
| What percentage of your working time is spent managing patients as opposed to research or administrative functions? | | |
| 70% or more | | 1 |
| Less than 70% | | 2 ***>>Close*** |

|  |  |  |
| --- | --- | --- |
| **D5** | **affiliation with other companies** | |
| Are you, or is any member of your household, currently employed by or affiliated with a pharmaceutical company, a healthcare or medical equipment manufacturer, serving as a clinical investigator, consultant, researcher or in any other capacity? | | |
| Yes | | 1 ***>>Close*** |
| No | | 2 |

**main screening questions**

Just for reference, chronic back pain is usually defined as lower back pain that persists for 12 weeks or longer, even after an initial injury or underlying cause of acute low back pain has been treated.

|  |  |  |
| --- | --- | --- |
| **s1** | **LBP management** | |
| Are you personally responsible for the management and treatment of patients with chronic severe lower back pain? | | |
| Yes | | 1 |
| No | | 2***>>Close*** |

|  |  |  |
| --- | --- | --- |
| **s2** | **LBP management [Do not ask in uk]** | |
| Do you treat the majority of your chronic severe lower back pain patients in an out-patient setting or in an in-patient setting? | | |
| Out-patient setting | | **1** |
| In-patient setting | | **2*>>Close*** |

|  |  |
| --- | --- |
| **s3** | **LBP management** |
| How many chronic severe lower back pain patients do you see in a typical month? | |
| ………………. patients | |

***>>CLOSE if <5***

|  |  |  |
| --- | --- | --- |
| **s4** | **lbp TREATMENT** |  |
| Are you personally responsible for initiating opioid treatments in patients with chronic severe lower back pain? | | |
| Yes | | 1 |
| No | | 2 ***>>Close*** |

|  |  |  |
| --- | --- | --- |
| **s5** | **LBP treatment** | |
| Which of the following medications are you currently prescribing for patients with severe chronic lower back pain? (MODERATOR NOTE: Generic names in bold / brand names in (brackets). Please refer to full product list below for all generic names and brand names by country) | | |
| Oxycodone oral prolonged release  (Oxycontin / Oxygesic [PN: DE only] + Generics) | | 1 |
| Oxycodone-Naloxone  (Targin [PN: not in UK] / Targinact [PN: in UK] + Generics) | | 2 |
| Tapentadol prolonged release  (Palexia SR / Yantil [PN: ES only]) | | 3 |
| Morphine oral prolonged release | | 4 |
| Hydromorphone oral prolonged release  (Jurnista [PN: not in UK and IT] / Palladone SR [PN: in UK] + Generics) | | 5 |
| Fentanyl Patches  (Durogesic + Generics) | | 6 |
| Buprenorphine patches  (Butrans [PN: in UK] / Norspan [PN: in DE] / Transtec [PN: in SP, IT and UK] + Generics) | | 7 |
| Ossicodone + paracetamolo [PN: in IT only] (Depalgos [PN: in IT only] + Generics) | | 8 |
| Buprenorfina cerotto [PN: in IT only]  (Busette [PN: in IT] + Generics) | | 9 |
| None | | 98 ***>>CLOSE*** |
| Don’t know | | 97 ***>>CLOSE*** |

***>>Multiple choice***

***>>CLOSE if code 3 (Palexia SR/Tapentadol prolonged release) not selected***

***>> CLOSE if codes 97-98 selected***

**Appendix 1.2 – Patient screener**

**Demographics**

Before the market research interviews take place, I would like to ask you a few questions to determine your suitability for this market research project

|  |  |  |
| --- | --- | --- |
| **D1** | **location** | |
| United Kingdom | | 1 |
| Spain | | 2 |
| Italy | | 3 |
| Germany | | 4 |
| Other | | 99 ***>> Close*** |

|  |  |  |
| --- | --- | --- |
| **D2** | **age** | |
| Under 18 | | 1 ***>> Close*** |
| 18-24 | | 2 |
| 25-34 | | 3 |
| 35-44 | | 4 |
| 45-54 | | 5 |
| 55-64 | | 6 |
| 65-74 | | 7 |
| 75+ | | 8 ***>> Close*** |

***>> Aim to recruit patients of different ages***

|  |  |  |
| --- | --- | --- |
| **D3** | **affiliation with other companies** | |
| Are you, or is any member of your household, currently employed by or affiliated with a pharmaceutical company, a healthcare or medical equipment manufacturer, serving as a clinical investigator, consultant, researcher or in any other capacity? | | |
| Yes | | 1 ***>>Close*** |
| No | | 2 |

**main screening questions**

|  |  |
| --- | --- |
| **s1** | **LOWER BACK PAIN diagnosis** |
| Approximately how long ago were you first diagnosed with severe chronic lower back pain?  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ months/years | |

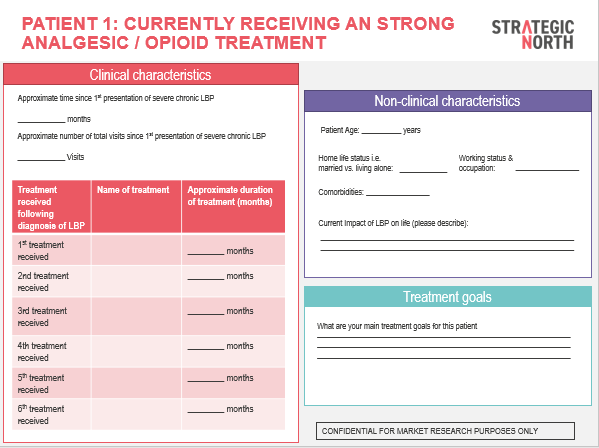
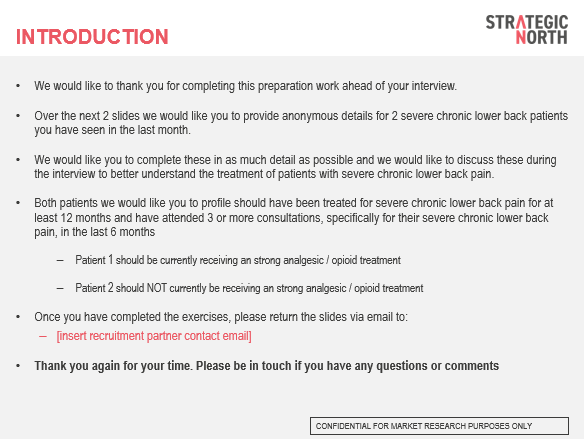
***>> CLOSE if <12 months***

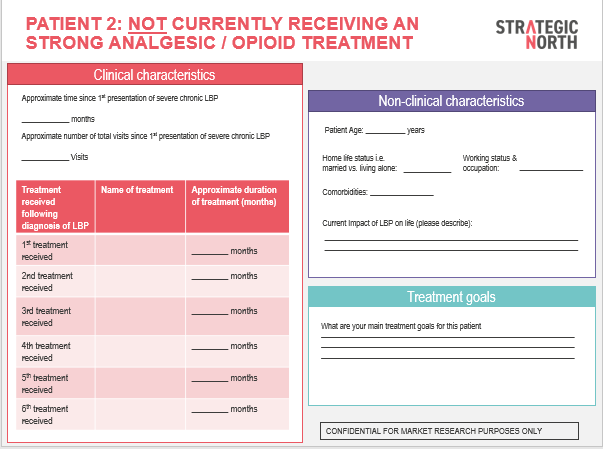
|  |  |  |
| --- | --- | --- |
| **s2** | **LBP treatment** | |
| Which of the following medications are you currently taking / or prescribed for your severe chronic lower back pain? (MODERATOR NOTE: Generic names in bold e.g. Tapentadol prolonged release / brand names in (brackets) e.g. (Palexia SR). Please refer to full product list below for all generic names and brand names by country) | | |
| Oxycodone oral prolonged release  (Oxycontin / Oxygesic [PN: DE only] + Generics) | | 1 |
| Oxycodone-Naloxone  (Targin [PN: not in UK] / Targinact [PN: in UK] + Generics) | | 2 |
| Tapentadol SR / tapentadol prolonged release  (Palexia SR / Yantil [PN: ES only]) | | 3 |
| Morphine oral prolonged release | | 4 |
| Hydromorphone oral prolonged release  (Jurnista [PN: not in UK and IT] / Palladone SR [PN: in UK] + Generics) | | 5 |
| Fentanyl Patches  (Durogesic + Generics) | | 6 |
| Buprenorphine patches  (Butrans [PN: in UK] / Norspan [PN: in DE] / Transtec [PN: in SP, IT and UK] + Generics) | | 7 |
| Ossicodone + paracetamolo [PN: in IT only] (Depalgos [PN: in IT only] + Generics) | | 8 |
| Buprenorfina cerotto [PN: in IT only]  (Busette [PN: in IT] + Generics) | | 9 |
| None | | 98 ***>>CLOSE*** |
| Don’t know | | 97 ***>>CLOSE*** |

***>>CLOSE if only codes 97-98 selected***

***Quota: n=3 patients MUST be currently taking Tapentadol prolonged release (Palexia SR) (code 3)***

**Appendix 2**

**Appendix 2.1 – GPs homework task**



**Appendix 3**

**Appendix 3.1 – GP discussion guide**

|  |  |
| --- | --- |
| Section 1 | |
| **Title** | **Introduction & perceptions of treating severe chronic LBP** |
| **Timings** | IDIs / TDIs: 5-10 minutes  Mini-group: 15 minutes |
| **Objectives** | * Introductions, understanding the role of the HCP and high-level perceptions of chronic severe LBP management |

*Thank you for agreeing to take part today in the discussion today. I’d like to start by asking you to briefly introduce yourself and your current role.*

* To start, please can you give me a brief description of the type of practice you work in and the mix of patients that you treat
  + Type of centre/office, public vs. private work
  + How much of your workload is made up by patients with chronic pain?

*As mentioned previously the main focus of our discussion today is severe chronic lower back pain…*

* How would you personally define severe chronic lower back pain? Allow spontaneous response and then probe
  + How do you differentiate this from mild / moderate chronic pain in clinical practice?
    - How do you assess pain severity?
  + At what point do you consider pain to be ‘chronic’? Why?
* How many patients with severe chronic lower back pain do you see in a typical month?
  + What proportion of these had been seen previously for their lower back pain?
* How frequently do you come across patients with severe chronic lower back pain who frequently re-present with complaints about their unresolved pain? (e.g. 3+ presentations in a 6-month period)
* What three adjectives would you use to describe how you feel about managing patients with severe chronic lower back pain?
  + For each adjective ask: Why?

|  |  |
| --- | --- |
| Section 2 | |
| **Title** | **Patient Journey overview & understanding decision making in severe chronic LBP** |
| **Timings** | IDIs / TDIs: 20 minutes  Mini-group: 45 minutes |
| **Objectives** | * Understand what PCPs think and feel about managing patients who have repeat consultations due to severe chronic LBP which isn’t fully controlled * Build a high-level view of the severe chronic LBP patient journey and all key touchpoints * Understand specific goals, challenges and drivers of decision making as well as how these evolve as the patient proceeds through the journey from first consultation through to prescription of strong analgesics |

*I would now like to understand in detail your typical approach to treating and managing patients with severe chronic lower back pain and how this changes when pain remains unresolved. I’m going to map this out onto the flipchart. Can you start by telling me about that first consultation…*

Moderator to work with respondent(s) to map out the typical journey capturing details on a flipchart

MODERATOR NOTE: Guide the physician through the patient journey, allowing them to speak freely but prompt to ensure coverage of each of the following steps.

* Initial presentation
* First re-presentation
* Subsequent presentations
* Point at which a strong analgesic is used

MODERATOR NOTE: Probe at each key stage described by the physician to understand:

**What happens:**

* What leads the patient to present? (e.g. symptoms, functional issues, QoL complaints)
* Questions asked by the doctor
* Investigations / tests done
* Treatment decision made (including formulation & dosage) and WHY?
  + Rationale for titration vs treatment switch
  + Treatment goal
* Advice given to patient
* If other HCPs/specialties are involved and what their role is

**How the physician feels at different stages of the journey:**

* Key concerns about the consultation, patient or treatment
* Use mood board (showcard 1) to understand how physician feels at each key stage and how this changes over time

**The relationship with the patient:**

* How the relationship with the patient changes over time
* How the physician thinks the patient feels at different stages
* Any concerns that the physician has about what the patient is telling them

**Time between consultations:**

* How this changes across the journey

**The role of different treatment options at each stage:**

* Understand when & why different therapies are used e.g. paracetamol, NSAIDs, Tramadol, opioid patches (e.g. fentanyl patches), opioid oral therapies, Palexia SR (tapentadol prolonged release)

**Specific strong analgesic/opioid considerations:**

* When first considered and why
* Considerations made before initiating a patient
* When first initiated and why
* Initial dosage and approach to titration vs switching therapy
* Considerations regarding AE monitoring
* Rationale for selection of one strong analgesic/opioid over another (which patient types? When in the treatment journey?)
* Rationale for use of patch vs oral (which patient types? When in the treatment journey?)

|  |  |
| --- | --- |
| Section 3 | |
| **Title** | **Real patient journey deep dives** |
| **Timings** | IDIs / TDIs: 15 minutes  Mini-group: 30 minutes |
| **Objectives** | * Enrich patient journey overview by deep diving into 2 real world (anonymised) severe chronic lower back pain patients * Understand key PCP and patient goals anchored at specific points experienced in their severe chronic LBP journey * Uncover key choice cues and considerations leading to prescription of strong analgesics |

*I now want to build upon our understanding of the severe chronic lower back patient pathway, using your homework task to specifically focus on some real patients you have managed.*

*Please remember that during the discussion patient confidentiality must be maintained and no patient identifying information must be disclosed.*

*MODERATOR NOTE: For group discussions focus on 2 x non-strong analgesic/opioid patients and 2x strong analgesic/opioid patients (ensuring 1 tapentadol prolonged release (Palexia SR) patient) – aim to select one patient from each respondent.*

*FOR GROUP DISCUSSIONS: Thank you all for completing your pre-work task these are all very useful. For the purposes of our discussion today we have selected a few of these to talk about in more detail.*

*FOR IDIS: Thank you for completing your pre-work task. In the next section I would like to talk about each of these in a bit more detail.*

For each patient, ask the physician who provided the homework to describe:

* A brief overview of this patient’s journey
* The major challenges associated with managing the patient
* How HCP felt about treating the patient
* The relationship with the patient and how this changed over time
* Rationale for initiation of each different therapy
* The patient’s experience on each therapy

*If not a strong analgesic/opioid patient:*

* Why patient has not been considered for a strong analgesic/opioid at this stage

*If a strong analgesic/opioid patient:*

* At what stage a strong analgesic/opioid was first considered vs when it was actually initiated
* What the final trigger for using a strong analgesic/opioid was
* If not tapentadol prolonged release (Palexia SR): Why not?
* If tapentadol prolonged release (Palexia SR): Why?

*FOR GROUP DISCUSSIONS: Ask other respondents to comment on how much they can relate to the patient being described:*

* Is this a typical patient?
* What considerations would you have made for this patient?
* Do you have a patient like this? What was your management approach?

|  |  |
| --- | --- |
| Section 4 | |
| **Title** | **Understanding drivers & barriers of prescribing strong analgesic treatments including Palexia SR** |
| **Timings** | IDIs / TDIs: 15 minutes  Mini-group: 30 minutes |
| **Objectives** | * Explore rational and emotional perceptions of current treatments available to treat chronic severe LBP patients * Uncover and build upon key drivers and barriers of tapentadol prolonged release (Palexia SR) * Understand key belief and behavioural shifts required to drive earlier and wider use of tapentadol prolonged release (Palexia SR) in appropriate patients |

*I’d now like to focus specifically on the different strong analgesic/opioid treatments available to treat severe chronic lower back pain.*

*First I would like you to complete the following sentences for Tramadol, Fentanyl patches & tapentadol prolonged release (Palexia SR).*

* + *The best thing about X is…*
  + *The thing I’m most concerned about when prescribing X is…*
  + *I would prescribe X if…*
  + *I wouldn’t prescribe X if….*

*Probe to understand rationale*

**Drivers for strong analgesics & Tapentadol prolonged release (Palexia SR)**

* When is the optimum time for initiating a strong analgesic/opioid therapy? Why?
  + Is this different for patches vs oral? Why?
* What are your **top 3** goals/priorities when initiating a strong analgesic/opioid treatment? **Why?**
* Are there any patient types or situations where you might choose a strong analgesic/opioid treatment earlier in the pathway?
  + If so, what are the key factors that would lead to this decision?

**Barriers for strong analgesics & Tapentadol prolonged release (Palexia SR)**

* In what situation do you feel it is inappropriate to use a strong analgesic/opioid treatment?
* What considerations do you feel it is important to make before you prescribe a strong analgesic/opioid treatment?
* Do you have any concerns with using strong analgesics/opioids? If so, what are they?
  + Are you aware that any of your colleagues have concerns with strong analgesics/opioids?
    - If so, what are they?
* What concerns do patients have about strong analgesics/opioid treatments? Explore fully
  + Where do patients seek information? How do they make an informed decision?
  + What additional information would be useful to help patients make an informed decision
* What are the limitations / drawbacks of strong analgesic/opioid therapies compared to other pain medications you prescribe?

**What must be true to prescribe strong analgesics/opioids earlier in the pathway?**

* What would need to happen for you / other physicians to consider a strong analgesic/opioid earlier in the pathway (for appropriate patients)? Allow spontaneous response, then probe:
* Specific characteristics of the strong analgesic treatment?
* Changes in evidence, guidelines, other treatment options?
* What the patients communicates / says?
* Changes in funding and reimbursement?

**Perceptions of Tapentadol prolonged release (Palexia SR)**

*Now I’d like to talk specifically about tapentadol prolonged release (Palexia SR) and its use in adults with severe chronic lower back pain. Please take a few moments to complete the following exercise. We would like to understand your opinion on:*

1. *Who is the prime patient type for tapentadol prolonged release?*
2. *When in the treatment pathway is the optimal time for tapentadol prolonged release to be prescribed?*
3. *Why should tapentadol prolonged release be chosen at this point / for these patients?*

*Moderator to allow respondent a few minutes to complete the exercise and then probe to understand the PCP’s rationale*

* How would you explain what type of therapy *tapentadol prolonged release* is to a fellow doctor?
  + Probe to explore how the respondent classifies tapentadol prolonged release (Palexia SR) / if they see it as the same as classical opioids
* How would you explain *tapentadol prolonged release* to a patient? (If not previously covered in conversation)
* What difference do you see between tapentadol prolonged release and other strong analgesics?
* In what situations do you select tapentadol prolonged release over other therapies? Why?
  + In what situations might you select tapentadol prolonged release earlier in the treatment pathway (for appropriate patients)?
* In what situations would you switch from tapentadol prolonged release to a different therapy? Why?
* In what situations do you feel it is inappropriate to use tapentadol prolonged release?

**>> THANK AND CLOSE.**

**Appendix 3.2 – Patient discussion guide**

|  |  |
| --- | --- |
| Section 1 | |
| **Title** | Introduction and rapport-building |
| **Timings** | 5 minutes |
| **Objectives** | * To build rapport with the patient and make him/her feel more comfortable |

***>> MODERATOR NOTE: RED TEXT INDICATES MODERATORS NOTES – DO NOT READ OUT TO RESPONDENTS***

*Thank you for taking the time to take part in this interview. To begin with, without revealing your full name…*

* Please tell me a little about yourself
  + Family / home-life – partner, children, home situation etc.?
  + Working / not working / retired – occupation, if working?
  + How do you enjoy spending your time – hobbies / interests etc.?
* How long have you been suffering from lower back pain?
* How is your lower back pain today?
  + Rate on a scale of 1-10 (10 being the most severe pain you can imagine)
  + Is this a typical day?
    - Why? / Why not?
* How do you currently manage your lower back pain?
  + What treatments do you take and when?
  + Other than medication, what else do you do to manage your lower back pain?
* How often do you see your PCP / GP about your chronic lower back pain?
  + Do you suffer from any other illnesses? How are these treated?

|  |  |
| --- | --- |
| Section 2 | |
| **Title** | Patient experience of living with severe chronic lower back pain |
| **Timings** | 10 minutes |
| **Objectives** | * To understand what life is like living with severe chronic lower back pain * To explore how patient’s think and feel about their treatment |

*To start with I would like to understand a bit about what life is like when you have severe chronic lower back pain…*

* Could you take a look at these images (Share showcard 1 – mood board) and, without too much thought, tell me what images you feel represent what life is like with severe chronic lower back pain?
* How, if at all, did your life change after you started suffering from severe chronic pain in your lower back?
  + Explore generally and then if not covered, probe to explore impact on:
    - Family
    - Work
    - Social life
    - Sport/leisure activities
* What is a typical day like when you are suffering from severe chronic lower back pain?
  + What is a good day like?
  + What is a bad day?
  + Ask them to compare the level of pain on good days, bad days and typical days using 1-10 rating (10 being the most severe pain you can imagine)
* What has been your biggest hope throughout your experience with lower back pain?
  + Why were you hoping for that?
* What was your relationship like with your GP through the course of your chronic severe lower back pain? Probe to understand how this has evolved over time (covering both positive and negative aspects)
* What have been your primary sources of information to support you in managing your lower back pain?
* Have you ever been hospitalised because of your lower back pain? How many times?
  + Have you ever had to go to the ER/A&E because of a pain attack/pain crisis? How many times has this happened?

|  |  |
| --- | --- |
| Section 3 | |
| **Title** | Patient Journey Exploration |
| **Timings** | 30 minutes |
| **Objectives** | * To build a more in-depth understanding of patients’ thoughts and experiences at each stage of the patient journey * To understand their major pain points, their feelings about treatment decisions and also, their experiences with primary care |

*Show RCF1 to the patient (RCF= Respondent Completion Form)*

*We would like to understand a little bit more about you and your journey of care with chronic severe lower back pain. In front of you, you will see a piece of paper with a timeline. The point on the left is when you first started experiencing lower back pain before you went to see the doctor. The point on the right represents today. At the moment this timeline is blank, I’d like you to help me fill in the blanks so we can understand your journey of care.*

*Everything that we discuss today will be confidential - although we may share your journey with the commissioning pharmaceutical company, you will not be identifiable to them in any way.*

*Think back to immediately prior to your diagnosis and note down the following key points up until today:*

* ***Key milestones / touch points*** *– we would like to understand the key points along your journey including* ***which healthcare professionals you saw*** *since diagnosis* ***and******how frequently****,* ***treatments taken*** *(either over the counter or prescribed by your doctor) and* ***any other milestones*** *you feel are relevant*
* ***Highs and lows*** *- Draw a line to reflect your highs and lows in the journey up to the present day. To give context, please include any life events / experiences you have had throughout the journey. We want to understand the impact that severe chronic lower back pain has had on your life*

Moderator to allow patient a few minutes to complete RCF1 before asking the following questions

* First of all, can you give me an overview of your journey with severe chronic lower back pain and describe what you felt were the key milestones in your journey with severe chronic lower back pain?
  + Which consultations most stick out in your mind?
  + Why are these the most memorable events?
* Can you tell me about when you first started experiencing severe chronic lower back pain?
  + *>> Moderator to allow the patient to talk freely and openly. Probe on the following only if necessary:*
    - When was it?
    - How did it feel?
    - What impact did it have on your life? (Work, family, social life)
* Before you went to see a doctor did you do anything to try to stop the pain?
  + *>> Moderator to allow the patient to talk freely and openly. Probe on the following only if necessary:*
    - Did you use over the counter pain relief? Which ones? What doses?
    - How long were you self-medicating in this way?
    - Did you seek any non-pharmacological pain relief?
* Did you seek advice or treatment from anyone before going to see your GP?
  + Probe: Physiotherapist, chiropractor, acupuncture
* How much time passed before you initially went to see your GP?
  + Why did you wait this long?
  + What eventually made you go to see the GP?

**General Probes for key touchpoints / milestones**

MODERATOR NOTE: Get the patient to walk you through their journey in detail. Allow the respondent to talk openly and freely but use the detailed probes to help guide the conversation when necessary. Ensure good coverage across all elements of the journey: The initial consultation, first re-presentation, subsequent representations, strong analgesic/opioid prescription

At each stage…

Why did the patient go to see the GP:

* How much time passed before you went back to see a doctor?
  + Why did you wait this long?
* What eventually made you decide to go back to see the doctor?
  + Also probe to understand if they saw a PCP / GP or another specialty
* How would you describe the impact your lower back pain was having on your life:
  + - Physically
    - Emotionally
    - Socially i.e. with family, friends, work, ability to do sport/leisure
* What were you hoping the doctor would be able to do?
  + How confident were you that your doctors could support you to achieve your goals? Why?

What happened at the consultation:

* What happened at that consultation?
  + How did the conversation go?
    - How did you describe the problem with your back?
    - What questions did the doctor ask?
    - Was there anything that you didn’t say that you wish you had?
    - To what extent did you feel listened to / understood by your doctor?
  + Did the doctor do any tests?
    - Which tests? For what purpose?
  + Did the doctor explain what they thought the problem was?
    - How did they explain it?
  + Did the doctor prescribe a treatment?
    - What did they prescribe? Why?
    - What other treatment options were discussed?
    - What did you know about the treatments discussed at this point?
    - Were there any treatments either you or your physician ‘ruled out’ at this point? Why?
    - What role did you play in the doctor’s decision to prescribe or not prescribe certain treatments?

How did the patient feel:

* How did you feel the consultation went?
  + What were your expectations at this point? What did you want to achieve?
  + Did you leave with any concerns?
  + Did you feel differently about your back pain after seeing the doctor?
* How did you feel about your GP / PCP and the care you were receiving at this point?
* How did you feel about the treatment you were receiving?
  + Did you have any specific concerns / uncertainties?
  + How did this change over time?

MODERATOR NOTE: Probe specifically to understand how the patient’s feelings and relationship with the GP changed over time

* How long did this whole process take?
  + How much time was there between appointments?
  + How did you feel about how long this was taking?
* How did your hopes / aspirations / goals concerning treatment evolve over time as you had more consultations?
* To what extent did your communication with your doctor change over time?
  + Did you begin to give more or less information? Why? **Probe to understand if the patient started to use different language to describe the impact of their LBP**
  + Did you consider changing your doctors / asking for a referral? Why / why not?
    - When did this happen?
* How did your knowledge about the treatment and management of lower back pain change?
  + What treatments were you aware of that might be potential options for your lower back pain?
  + What did you know about these treatments?
  + What information sources did you use? **MODERATOR NOTE: KEY QUESTION**

MODERATOR NOTE: Probe specifically on the circumstances surrounding strong analgesic/opioid prescription

**1st strong analgesic/ prescription**

* What circumstances led up to the prescription of [insert name(s) of strong analgesics / opioid patient has received]?
* How frequently did you / do you take [insert name of strong analgesics / opioid]? What dose? How did you / do you take it?
* Did you ever not take your strong analgesic / opioid prescription? Why?
* Did the dosage change?
* Describe your overall experience on [insert name(s) of strong analgesics / opioid patient has received]
  + How well did this treatment help you to meet your goals / aspirations?
* To what extent did you consider prescription of [insert name of strong analgesic / opioid] a milestone in your journey with lower back pain? Why?

**Strong analgesic / opioid switch**

* If the patient switched between opioids / strong analgesic therapies: What circumstances led to you switch from [insert name of strong analgesic / opioid] to [insert name of strong analgesic / opioid]?

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| Section 4 | |
| **Title** | Understanding perceptions of treatments and drivers & barriers of receiving strong analgesics treatments |
| **Timings** | 10 mins |
| **Objectives** | * Explore rational and emotional perceptions of current treatments available for severe chronic lower back pain * Understand in depth the patient’s real-life experience of treatments received up until initiation of strong analgesics * Uncover key drivers and barriers of using strong analgesics (including Palexia SR if appropriate) from a patient perspective |

*I’d like to understand what you think about the different treatments you have received in your journey with lower back pain*

*For each of the treatments you have received please complete the following sentences:*

* *The best thing about receiving this was…*
* *With this treatment, I was most concerned about…*
* *I had most questions about…*

*I would now like to specifically discuss opioid pain killers more generally.*

* What opioid pain killers are you aware of?
  + What do you know about each of them?

Probe to explore:

* + What are the differences between them?
  + Were you aware of them before you were diagnosed with severe chronic lower back pain?
    - If so, what was your perception? And has this changed?
    - If not, at what point in your journey did you first become aware of them?
  + Where did you find out about these treatments?
  + To what extent did you perceive these treatments to be different vs. what you had previously received? Probe to understand perceived pros and cons of these treatments
  + Was there anything you were uncertain / concerned about these treatments?
* Were there any points in the journey where opioid treatments were considered by you and your doctor but you decided to start a different treatment? If yes:
  + What treatment did you start instead?
  + Why did you and your physician choose another treatment?
  + How did you feel about this?
* Which specialty of doctor prescribed [insert name of strong analgesic/opioid received] to you in the first place?
  + How did this doctor describe the treatment to you?
  + Probe to explore:
  + What questions did you have?
  + Did you have any concerns?
  + To what extent were your uncertainties / concerns about receiving these treatments alleviated by the doctor? How?
  + What was the impact of your severe chronic lower back pain on your life at this point compared with earlier in your journey? To what extent did your HCP ask questions about this?
* At the point of prescribing [insert name(s) of strong analgesic/opioid received]:
  + How did you feel about this treatment?
  + How do you think your doctor felt about prescribing this treatment?
* Why might other patients suffering from severe chronic lower back pain NOT want to use opioid treatment?
  + What is your perspective on this?

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| Section 5 | |
| **Title** | Advice to patients & doctors |
| **Timings** | 5 mins |
| **Objectives** | * To understand the patient’s advice to other patients / HCPs managing severe chronic lower back pain |

*In the final part of the discussion I would like you to reflect on your journey and experiences with severe chronic lower back pain:*

* If a doctor asked for your advice about how best to engage / support patients with severe chronic lower back pain what would you say?
* If you could go back in time to the point where you first started experiencing low back pain, what advice would you give yourself?
* If you could go back in time to the point where you first started getting treatment for your low back pain, what information would you wish you had known?
* If you met someone who had recently started experiencing severe chronic lower back pain what advice would you give them to help them to navigate the healthcare system?

**THANK AND CLOSE**