

WPD-CPS-PSC-021 – US Division

In-Person Welcome Visits for Drug C

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1. Introduction/Purpose

This Working Practice Document (WPD) is intended for use by the Company Patient Support (CPS) Patient Support Center (PSC) associates for conducting and monitoring in person welcome visits as part of the ongoing support (adherence) program.

2. Scope

This WPD is applicable to the CPS PSC and other CPS functions that may require knowledge and training on conducting and monitoring in person welcome visits as part of the Drug C ongoing support (adherence) program.

3. Related Procedures/Forms/Appendices

Document #	Document Title
WPD-CPS-PSC-021_Appendix A	Monitoring Checklist for In-Person Welcome Visits
WPD-CPS-PSC-021_Appendix B	Patient Navigator Checklist for In-Person Welcome Visits
WPD-CPS-PSC-021_Appendix C	Quality Check for In-Person Welcome Visit Monitoring

4. Acronyms/Abbreviations

Acronyms/Abbreviation	Full Name / Title
AE	Adverse Event
AD	Associate Director
BI	Benefits Investigation
CE	Coverage Exception (i.e., Prior Authorization, Appeal, etc.)
CRM	Customer Relationship Manager
DST	Disease State Team
ERC	Ethics, Risk & Compliance
FAQs	Frequently Asked Questions
HCP	Health Care Provider
HCS	Human Care Systems (ongoing support vendor)
ISI	Important Safety Information
CPS	Company Patient Support
PE	Performance Excellence
PHI	Protected Health Information
PI	Prescribing Information
PN	Patient Navigator
PSC	Patient Support Center
QA	Quality Assurance
TC	Technical Complaint
TL	Team Lead



5. In-Person Welcome Visits for Patient Navigator

Responsibility	Task
Offering the In Person Welcome Visit	<ul style="list-style-type: none"> As part of the ongoing support program, if a patient opts into full adherence support (mail and TCPA; email optional) they may be offered the In-Person Welcome Visit <ul style="list-style-type: none"> If the patient does not agree to the in-person visit, the PN can offer a phone or video call (when available) as an alternative The in-person visit should be conducted within the first 2-4 months of the patient starting on therapy The PN will review each area of the Welcome Kit as part of the in-person visit PNs may interact with patients for a one time in person welcome visit, as part of the ongoing support program, provided certain parameters are in place. These include, but are not limited to: <ul style="list-style-type: none"> Locations: PN meeting with patients to take place in appropriate, mutually aligned meeting places address documented in CRM: <ul style="list-style-type: none"> Only meet patients in public places conducive for a private discussion. Arrive early and find a seating location away from high traffic areas and away from earshot distance from other individuals. Care must be taken to ensure patient or disease state information is not visible to other individuals. Do not disclose patient information to any third party. Meetings should not take place in an HCP office or hospital patient care spaces (including the waiting room) Do not meet in a patient or caregiver's home. May meet in libraries, coffee shops, senior centers, community centers, hospital lobby, hospital coffee shop, hospital common areas, and other free public spaces. <ul style="list-style-type: none"> Check the location of the in-person welcome visit to confirm hours of operation and that it meets privacy requirements. Transport: PN cannot/will not transport patient or caregivers to and from the visit PN must ensure that patient is opted into the Ongoing Support program and that all supporting documentation has been captured in CRM <ul style="list-style-type: none"> PN must document the patient's permission for in-person visit in the case notes Should the patient want a caregiver to attend, the PN should document permission from the patient in the CRM case notes (as with other Ongoing Support calls), including the name of the caregiver and the specific call/visit for which the patient has provided permission to attend PN will schedule the in person visit (as they would schedule any Ongoing Support call) and document the location (full address) of the visit in the call notes <ul style="list-style-type: none"> The visit should be scheduled from 8 am- 8pm ET, Monday-Friday, excluding holidays PN should remind the patient to bring their Welcome Kit to the visit. If the patient has not received the Welcome Kit, and visit is more than 3-5 business days out, PN offers to re-send the Welcome Kit. Otherwise, the PN will bring two Welcome Kits to the visit. Patient would receive a reminder phone call and SMS text message 1-2 business days prior to the visit.
Conducting the In Person Welcome Visit	<p style="text-align: center;">DOs (permitted activities):</p> <ul style="list-style-type: none"> PN must be dressed professionally. PN arrives at the location early, finds a private location and ensures all patient and disease state information is not visible to the public.



	<ul style="list-style-type: none"> ○ If there is not a place to sit and/or the location is not conducive to a private discussion, the PN waits for the patient to arrive and then collectively choose a new public place. The full address of the new location along with the reason for re-locating should be included in the CRM notes. • PN should call the patient via system or if the location does not have internet, call into the PSC to advise of arrival and location <ul style="list-style-type: none"> ○ After 30 minutes from the scheduled start time, if the patient doesn't arrive and the call attempt is unsuccessful, the PN may leave and the visit may be made up with a phone or video call (when available). The unsuccessful visit should be documented in the CRM notes. • PN must validate all patient information prior to start of meeting (HIPAA verification), as they would in an Ongoing Support call. • PN will use the Welcome Kit and as needed, approved call guide(s), FAQs and barriers to ensure that only appropriate items are covered. • PN provides patient education using only FUSE-approved materials. The PN will also bring an extra copy of the Welcome Kit for use during the discussion in the event that the patient has misplaced/not received their copy. • PN may provide information that was previously reviewed for patients regarding reimbursement journey (i.e., status of BI and/or CE). • PN to offer ISI, PI & Medication Guide, as required. • PN is to document case notes immediately following meeting in CRM. <p style="text-align: center;">DON'Ts (not permitted activities)</p> <ul style="list-style-type: none"> • PN cannot purchase any meals, drinks, snacks, etc. for patients and/or caregivers at any time before, during or after the meeting. • PNs cannot accept any offered meals, drinks, snacks, etc. from a patient and/or caregiver at any time before, during, or after the meeting. • PN should not leave laptop or any CPS information unattended. • PN should not write any PHI down. • PN should not disclose patient information to any third party. • PN may not provide medical or clinical advice or view/interpret or discuss medical charts or records and may not otherwise assist in any clinical or treatment activity • PN must not encourage patients who have voiced a desire or intent not to initiate or discontinue therapy (for example, due to an adverse event or for other reasons) to continue such treatment. These patients must always be referred to their treating HCP. • PN may not provide support related to non-company or other company products. • PN may not promote any product. <p style="text-align: center;">Managing Disclosure of AE/TC or Off-label inquiry:</p> <ul style="list-style-type: none"> • AE/TC: If there is a disclosure of an adverse event, the PN may use their laptop to report it, the PN must document within the PVI tool as soon as possible and within 24 hours. Include the PVI number in the CRM case notes • Off-label Inquiry: In the event a PN receives a clinical off-label inquiry, they must refer the patient to their treating HCP.
Travel Logistics & Reimbursement	<ul style="list-style-type: none"> • All travel and expenses should follow standard company guidance. • PN will receive a company card for the purposes of expenses related to their own travel, hotel, and breakfast/lunch/dinner expenses during an In-Person Welcome Visit. • The PN documents the expected travel days with Workforce Management to align backup coverage. • Upon return to the office, the PN will document and submit expenses via the company-approved reporting tool, following Company Expense policies.



5.1 Monitoring of Patient Navigator In-Person Welcome Visits

Responsibility	Task
Observer	The following roles are permitted to observe in-person welcome visits: <ul style="list-style-type: none"> • Drug C PSC Operations (Director, AD & TLs) • CPS ERC • CPS PE Analysts for Drug C • CPS DST for Drug C • Other designated roles
Observer	Preparation of Field Observation in preparation for observation the Observer will: <ul style="list-style-type: none"> • Connect with Drug C PSC Operations to check which PN(s) may have a visit scheduled. Drug C PSC Operations to provide the Observer with the time, date, and location of the visit. • Review results of previous observation(s) for necessary follow-up.
Observer	Execution Frequency of Field Observation <ul style="list-style-type: none"> • Each respective PN will have one (1) live observation per calendar year. More frequent sessions can be conducted if required. • First observations must occur within first two (2) in-person visits.
Observer	Documentation <ul style="list-style-type: none"> • Observer completes the Monitoring Checklist for each visit within three business days of observation. • Monitoring Checklist is reviewed with PN within three business days of observation.
Observer	Archiving Monitoring Checklists <ul style="list-style-type: none"> • Monitoring Checklists will be stored on a Restricted Teams site titled "In Person Visit Monitoring" • PN Acknowledgement will be kept on file and stored on a Restricted Teams site titled "In Person Visit Monitoring" • Only the following teams are to have access to the Restricted Teams site: PSC Operations for Drug C (Director, AD and TLs) and Performance Excellence
Patient Navigator	Acknowledgement of Monitoring Checklist <ul style="list-style-type: none"> • PN will acknowledge the receipt of the monitoring checklist report via email.
CPS PE	CPS-PE – performs a QA check to ensure that the observations are being carried out as specified. Annually CPS-PE will verify that each PN has been observed at least once, and that the first observation was within the first 3 months of facilitating in-person welcome visits.

6. Training Requirements

This WPD is applicable to the following Functional Roles (list all that apply)	Type of Training Required (Read & Understand, eLearning Module, etc.)
Drug C Patient Navigators	Read & Understand
Drug C PSC Operations (Director, AD & TLs)	Read & Understand
CPS ERC	Read & Understand
CPS PE Analysts for Drug C	Read & Understand
CPS DST for Drug C	Read & Understand
CPS QA	Read & Understand

Note: If a CPS role not listed in the above training grid assists with monitoring in-person welcome visits they will need to complete the required training.

7. Review Cycle

This WPD will be reviewed annually or sooner if changes are required.

