CodeX™ REMS Integration Use Case

5th Public Call
May 24, 2022

https://www.hl7.org/codex/
https://confluence.hl7.org/display/COD/CodeX+Home
If This Is Your First Time Attending...Welcome!

- **REMS Integration Use Case - You are Here!**
  - The home of the community seeking an automated, efficient, and effective REMS ecosystem
  - Public call participation is open to all interested parties

- **CodeX - an HL7 FHIR accelerator**
  - Use case-driven approach to implement and expand CodeX clinical specialty data standards

- **mCODE = minimal Common Oncology Data Elements**
  - A small number of data elements (~90)
    - ... enable a large number of use cases
    - ... allow high-fidelity use and reuse of data with low incremental burden

New to FHIR? [https://wiki.hl7.org/FHIR_Starter](https://wiki.hl7.org/FHIR_Starter)
## Agenda

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenters</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome and REMS Integration Use Case Introduction and Review</td>
<td>Kelee Petzelt</td>
<td>5 minutes</td>
</tr>
<tr>
<td>High Level Roadmap and Pilot Discussion</td>
<td>Kelee Petzelt, Nicole Ng</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Understanding NCPDP Efforts and How HL7 FHIR Enhances Process</td>
<td>Pooja Babbrah</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Demo of REMSv0.3 REMS Administrator Workflow</td>
<td>Sahil Malhotra</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Demo Discussion</td>
<td>Kelee Petzelt</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Next Steps</td>
<td>Kelee Petzelt</td>
<td>5 minutes</td>
</tr>
</tbody>
</table>
REMS: Pilot Pass Opportunity

- Welcome New Participants
- If there are efforts within your organization that would benefit from creating a pilot, we can work to create a “pilot pass” to offer your organization insight into the leadership community
- Join weekly leadership meetings to inform pilot development and use case next steps
- Part of our commitment to transparency and collaboration
REMS: Call to Action

Explore how the REMS community can harness the FHIR standard to develop open-source, interoperable REMS solutions that reduce stakeholder burden and address your needs.

Contribute your real-world expertise to REMS prototype development.

Consider opportunities to leverage this work in pilots to drive adoption in real-world healthcare settings.

- Join other upcoming REMS Public Calls
  Registration information is available on the REMS confluence page: https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration

- “Pilot Pass” Participation
  Offers an inside peek into member discussions and the ability to be hands on in the project – a fast track to membership through pilot opportunities. Collaborate with members on ideas and projects that may benefit from utilizing the prototype.

- Share your REMS implementation experiences and recommendations
  Champion a CodeX REMS Integration Use Case

- Spread the word to friends and colleagues and encourage them to participate

- Recognize the value of stakeholder-focused workflow input
  Examine prescriber and pharmacist workflows to identify and address gaps in reference implementation resources
  - Please email Kelee Petzelt (kelee.petzelt@pocp.com) with any ideas or requests
REMS: Challenge and Opportunity

Risk Evaluation and Mitigation Strategy (REMS)
A drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of a medication outweigh its risks

Challenge:
- **Lack of interoperability** hampers communication and coordination among REMS stakeholders resulting in delays in therapy, limited access to REMS drugs, and sub-optimal patient care
  - Several stakeholders are key in the prescribing and provision of REMS drugs to patients
  - The exchange of data supporting REMS implementation is unduly burdensome

Goal:
Create an automated, efficient, and effective REMS ecosystem with the **HL7 CodeX FHIR standards-based technical infrastructure**. This ecosystem will allow for REMS integration into workflow, enabling data sharing and reducing undue burden.
REMS Integration Use Case

Problem
- Multiple stakeholders play an important role in the REMS administration process:
  - Verification of variable completed REMS requirements
  - Dispensing the drug with no unified way to:
    - Coordinate the process
    - Share data among one another
- Gaps in data interoperability make REMS communication and coordination burdensome
- Not in current workflow - the complexity of these leads to increased burden for stakeholders and the healthcare system overall

Solution
- Leverage data standards and create a data infrastructure to integrate REMS processes into stakeholder workflows
- Facilitate integration, enabling:
  - Prescribers and pharmacists to:
    - Be alerted to a REMS requirement
    - Complete requirements (training, education, clinical actions)
    - Attest and easily confirm in workflow that REMS requirements have been met
  - Patients receive REMS drugs efficiently - without undue burden or delay - via effective, interoperable workflows across all REMS stakeholders
# Roadmap to REMS Pilot Implementation

<table>
<thead>
<tr>
<th>Design</th>
<th>Momentum</th>
<th>Planning</th>
<th>Pilot Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activities</strong></td>
<td><strong>Stakeholder Engagement</strong></td>
<td><strong>Pilot Planning - Contracting</strong></td>
<td><strong>Pilot Implementation</strong></td>
</tr>
<tr>
<td>Prototype Design and Iterations</td>
<td>Stakeholder Engagement</td>
<td>Pilot Planning - Contracting</td>
<td>Pilot Implementation</td>
</tr>
<tr>
<td>Research stakeholder roles</td>
<td>Identify key players – outreach</td>
<td>Interested pilot party discussion</td>
<td>Timeline focused implementation</td>
</tr>
<tr>
<td>Understand industry demand/processes</td>
<td>Remove barriers to pilot implementation</td>
<td>Pilot parameters set-synthetic data</td>
<td>Iterations to pilot product</td>
</tr>
<tr>
<td>Proof of concept discussions</td>
<td>Gauge opportunities to pilot</td>
<td>Contractual commitment discussion</td>
<td>Real-world issues and set back discussion</td>
</tr>
<tr>
<td>Understand industry barriers and gaps</td>
<td>Channel public call input/survey</td>
<td>Timeline creation discussions</td>
<td>Pilot phase to execution planning</td>
</tr>
<tr>
<td>Create Prototype</td>
<td>“Why” stakeholder group parameters</td>
<td>Brainstorm partners that may enhance pilot actors</td>
<td>Marketing and real-world education</td>
</tr>
<tr>
<td>Prototype iterations – technology focus</td>
<td>Industry engagement – events</td>
<td>Exploration of opportunities to utilize data</td>
<td>Redundancy and gap review</td>
</tr>
<tr>
<td>Technical validation processes – cyber security focus</td>
<td>Create workflow focused input.</td>
<td>Interoperability and transparency focus.</td>
<td>Launch</td>
</tr>
<tr>
<td><strong>Final Prototype Iteration</strong></td>
<td><strong>Identify Pilot Participants</strong></td>
<td><strong>Pilot Contracting</strong></td>
<td><strong>Product Launch</strong></td>
</tr>
<tr>
<td>Vision and concept organization</td>
<td>Identify Pilot Participants</td>
<td>Contracting and legal detail</td>
<td>Identify/address redundancy and gaps</td>
</tr>
<tr>
<td>Public call conversions to membership</td>
<td>Scope and process detail</td>
<td>Pilot planning and creation into EHR and PIS workflow</td>
<td>Continued member engagement</td>
</tr>
<tr>
<td>Member input focused iterations</td>
<td>Pilot opportunities</td>
<td>Discover any barriers or gaps to implementation</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Prototype iterations-final pilot phase</td>
<td>Pilot parameter whiteboarding</td>
<td>Continued research and iterations</td>
<td>Product launch discussion</td>
</tr>
<tr>
<td>Process and key stakeholders identified with key initiatives and next steps</td>
<td>Key actors identified in process</td>
<td>Gain any partners or necessary additions to enhance pilot</td>
<td>Continued added support from industry</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td><strong>Technical Validation</strong></td>
<td><strong>Process</strong></td>
<td><strong>Key Stakeholders</strong></td>
</tr>
<tr>
<td>Vision and concept organization</td>
<td>Technical validation processes – cyber security focus</td>
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<td></td>
</tr>
</tbody>
</table>
REMS Prototype Release Schedule

REMSv0.1  January 31
Prescriber Workflow

REMSv0.2  March 14
Prescriber and Pharmacist Interaction

REMSv0.3  April 25
REMS Administrator Workflow

REMSv0.4  June 6
Improvements to Existing Stakeholder Workflows & Initial Education Support

REMSv0.5  July 18
Potential Features*:
- Pharmacy Verification of REMS ETASU
- Extended Education Support
- Initial Patient Support

REMSv0.6  August 29
Potential Features*:
- Extended Patient Support
- Improvements to all Workflows and User Interfaces
- Expanded support of ETASU for TIRFs, Revlimid, and iPLEDGE

Complete Proof of Concept Phase  September 29

*FDA is seeking industry and community input for further direction on development for future prototype release (REMSv0.5 and REMSv0.6)
What We Are Hearing

- Non-Ideal Scenarios
  - Provider
  - Pharmacy
  - Patient Integration
- EHR interface

✓ Designees’ role in the REMS Process
✓ How to leverage and integrate NCPDP in this work
### History of NCPDP FDA REMS Efforts

- **2010**: NCPDP created a Risk Evaluation and Mitigation Strategies (REMS) reference guide using the Telecommunication Standard version 5.1
- **2011**: FDA launch REMS Integration Initiative
- **2015**: FDA Common REMS Platform Initiative

#### Common REMS Platform includes:

- **Catalog**: of electronic data standards for REMS operation/communication, maintained by FDA
- **Process**: to create and update standards to add to catalog

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REMS Integration Initiative | FDA
Building a Common REMS Platform (duke.edu)
https://www.fda.gov/media/106442/download
NCPDP REMS Related Standards: Prior Efforts

- NCPDP released implementation guide for REMS Transaction for the Telecomm standard in 2011
  - Telecomm standard is used by pharmacies to process claims; allowed pharmacies to use claims transaction to **electronically confirm that REMS requirement has been met and pharmacy can dispense the medication**
  - Currently not a “named” standard in legislation, but most pharmacies and intermediaries implemented the transaction through trading partner agreements
  - NCPDP also added a field to the most recently named SCRIPT standard (ePrescribing standard), Version 2017071
    - Added REMS status for prescriber
    - Allows for REMS initiation and Response
NCPDP REMS Related Standards: Current Efforts

- NCPDP SCRIPT Transactions
- NCPDP working to integrate REMS check into ePrescribing
- Current workgroup (MC REMS Workflow to Transactions Task Group Notes)
  - Scope - identify how NCPDP standards can be used to standardize REMS and reduce burden
    Building a Common REMS Platform

- Structured Product Labeling (SPL)
  - HL7 Standard specification
  - Data standard used to capture and share structured information about drug products
  - Will trigger in EHR to send initiation request to REMS administrator
  - REMS administrator approves or initiates question/answer sets
  - Once complete, new prescription is sent to pharmacy containing REMS authorization number

Building a Common REMS Platform (duke.edu)
REMS Pilot Wrap-Up (fda.gov)
Current REMS Process: Physician, Patient and Pharmacist

Drug Database? or CDS Hook

- Prescriber is notified of REMS

Can you use existing drug databases as "flag" to trigger CDS hook?

- Prescriber writes Rx for patient and gives patient REMS Contract to sign

Will prescriber "hold" eRx until REMS is approved?

- Pharmacist/Dispenser confirms prescriber REMS requirements

Multisource Drugs - 11 of 61 – How do we handle as Provider does not go by NDC

- Pharmacist/Dispenser contacts help desk and/or prescriber to obtain missing information

If doc sends eRx to pharmacy – should have some notification that REMS as been submitted

- Patient or caregiver counseled at pharmacy per REMS requirements

Is there a need for pharmacist to communicate back to provider if they have requirements to meet?

- Prescription filled/dispensed

Prescription filled/dispensed

- Patient monitoring, reporting and auditing

Including questions and comments we’ve heard from Pilot Pass participants!
Given the challenges and opportunities discussed over the past few calls, we continue to see a viable path forward for improving REMS integration. Next steps:

- Continue outreach to build a collaborative community
  - Gathering key stakeholder views and ideas to address these challenges and opportunities collectively, creating a pathway to piloting the prototype
  - Making iterations to the demo that you saw today based on your feedback and input

- Together as a community, we can better
  - Specify sources of burden by leveraging electronic integration
  - Leverage the CodeX FHIR accelerator community, continually iterating towards a better solution
Prototype REMSv0.3 – REMS Administrator

- Review REMSv0.3 Prototype
- Discussion and feedback
  - How well does this resonate with your real-world experience?
  - What's missing in the process?
  - What would you change?
  - Any other messaging ideas? Concerns?
- Next version update: Improvements to Existing Stakeholder Workflows & Initial Education Support
  - Any suggestions or ideas for the team to address as we continue developing this iteration?

www.fda.gov

Your feedback matters!
REMSv0.3 Demo
REMS Administrator Workflow
CodeX Risk Evaluation and Mitigation Strategies (REMS) Proof-of-Concept Prototype

Release version REMSv0.3: REMS Administrator Workflow

May 2022
Presented By: Sahil Malhotra
Discussion and Next Steps
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  Examine prescriber and pharmacist workflows to identify and address gaps in reference implementation resources
    - Please email Kelee Petzelt (kelee.petzelt@pocz.com) with any ideas or requests
Thanks for listening!
Addendum:
Prototype Background
CodeX Risk Evaluation and Mitigation Strategies (REMS) Proof-of-Concept Prototype

Release version REMSv0.3: REMS Administrator Workflow

May 2022
Presented By: Sahil Malhotra
Introduction

- **Initial REMSv0.1 was released on January 31st**
  - Release focused on Prescriber workflow and reducing burden
  - Uses Turalio - Requires lab tests and allows for pulling patient data out of the EHR
  - CodeX REMS project leverages existing Da Vinci Prior Authorization Solution

- **REMSv0.2 was released on March 14th**
  - Builds upon REMSv0.1 and focuses on pharmacy system setup and integration
  - Pharmacy system is based on third party open-source software*

- **REMSv0.3 was released on April 25th**
  - Focus on REMS Administrator setup and integration
  - REMS Administrator interface implemented on top of Da Vinci CRD Solution

* Open-source pharmacy software [https://github.com/LalanaChami/Pharmacy-Management-System](https://github.com/LalanaChami/Pharmacy-Management-System) used for demonstration purposes
Workflow Overview

1. Does the drug have REMS?
2. Submit prescription and REMS requirements
3. Pharmacy verifies REMS are met
4. Prescriber checks for status updates
New Features

1. Does the drug have REMS?
2. Submit prescription and REMS requirements*
3. Pharmacy verifies REMS are met*
4. Prescriber checks for status updates*

*Improved/new in v0.3
REMSv0.4 – What’s Next?

▪ **Community Engagement**
  - Work with the CodeX stakeholder community to plan and prioritize future prototype features
  - Leverage community engagement to inform technical decisions for features in progress

▪ **Education Support**
  - Explore modeling training/credentials in FHIR and leveraging existing training management approaches used by the community
  - Create questionnaire for credential data and pull credential data from the EHR to autofill the questionnaire

▪ **REMS Requirements Database**
  - Store ETASU (Elements To Assure Safe Use) alongside FHIR questionnaire data to explore FHIR ETASU modeling
  - Incorporate requirements-met and questionnaire results storage
  - Demonstrate how FHIR-based structured storage of ETASU and results can be used to inform REMS Administrator logic

▪ **Improving Existing Stakeholder Workflows**
  - Make updates to communications to leverage prescription data to determine whether REMS requirements have been met
  - Improve the user interface for the PIS (Pharmacy Information System) for easier demonstration of features
Technical Details

- **Test Electronic Health Record (EHR) – Java Springboot**
  - Hospital database containing medical information

- **CRD-request-generator – Javascript/Node**
  - Application to generate request to CRD

- **Coverage Requirements Discovery (CRD) - Java Springboot**
  - Accepts CDS hook and returns Card providing links to necessary documentation

- **Documentation Templates and Rules (DTR) - Javascript/Node**
  - SMART on FHIR app to load and auto-fill FHIR Questionnaire

- **Pharmacy Information System (PIS) - Typescript/Node**
  - Mock pharmacy system to demonstrate integrations with REMS use case
Sequence Diagram (Current)
Learn More: CodeX REMS Integration Use Case and Da Vinci Prior Authorization

- CodeX REMS Integration Use Case public confluence page: https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration

- Da Vinci hosts a monthly Community Roundtable
  - Link to past Da Vinci Video Presentations

- The three Da Vinci Prior Authorization Implementation Guides and public confluence pages containing information and links to the published guides:
  - Coverage Requirements Discovery (CRD)
  - Documentation Templates and Payer Rules (DTR)
  - Prior Authorization Support (PAS)
Installation

- **Installing the entire REMS project is as easy as running a few commands**
  - Servers are published to docker hub using docker images
  - Automated docker set up configuration process using Porter
  - Follow along with future demos (Initial install may take a while)

- **Steps:**
Addendum: Demo Screenshots
Select Patient and Medication

| Patient Select: | N/A |

**Demographics**

<table>
<thead>
<tr>
<th>ID: pa0115</th>
<th>Request: Choose an option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: William Order</td>
<td>Gender: male</td>
</tr>
<tr>
<td>Age: 6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID: pa0124</th>
<th>Request: Choose an option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Bobby Tables</td>
<td>Gender: male</td>
</tr>
<tr>
<td>Age: 25</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID: pa014</th>
<th>Request: Choose an option</th>
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<tbody>
<tr>
<td>Name: Theodor Roosevelt</td>
<td>Gender: male</td>
</tr>
<tr>
<td>Age: 75</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID: pa016</th>
<th>Request: Choose an option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Ada Wilson</td>
<td>Gender: female</td>
</tr>
<tr>
<td>Age: 45</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID: pa013</th>
<th>Request: Choose an option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Vlad Quinton</td>
<td>Gender: male</td>
</tr>
<tr>
<td>Age: 85</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ID: pa017</th>
<th>Request: (2163106) Turale 200 MG Oral Capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Jon Snow</td>
<td>Gender: male</td>
</tr>
<tr>
<td>Age: 25</td>
<td></td>
</tr>
</tbody>
</table>
Selection shows that drug has REMS
Open Patient Enrollment Form & Login
Patient Enrollment Form Opens

<table>
<thead>
<tr>
<th>Patient Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address Line 2</td>
</tr>
<tr>
<td>Telephone</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>Is the patient currently taking perazine (i.e., started prior to REMS enrollment)?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>If yes: Was this part of a clinical study?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriber Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address Line 2</td>
</tr>
<tr>
<td>Please visit <a href="http://www.tusalumni.org">www.tusalumni.org</a> or contact the TURALIO REMS Coordinating Center at 1-833-TURALIO (833-887-2546) to designate up to two additional REMS certified prescribers who can view, edit, and submit REMS paperwork for your TURALIO patients.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current Medication (including prescription, non-prescription and herbal or dietary supplements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check box if there are no current medications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hepatic Medical History</th>
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</thead>
<tbody>
<tr>
<td>Check box in this section if there is no hepatic medical history</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriber Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have reviewed and discussed the risks of TURALIO and the requirements of the TURALIO REMS with this patient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Provider Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature *</td>
</tr>
<tr>
<td>Name (Printed) *</td>
</tr>
<tr>
<td>Date *</td>
</tr>
<tr>
<td>NPI *</td>
</tr>
<tr>
<td>Type a value</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Attestation</th>
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</thead>
<tbody>
<tr>
<td>In order to receive TURALIO I must be enrolled in the TURALIO REMS. The TURALIO REMS will collect data to assess the risk of serious liver problems which can be severe and lead to death as described in the Patient Guide. I agree to enroll in the Patient Registry. I agree to review the Patient Guide. I must get blood tests to test my liver as directed by my healthcare provider. I agree to tell my healthcare provider if I have signs and/or symptoms of liver injury. My personal information will be shared to enroll me in the Patient Registry so that my health and any liver injury can be evaluated while I am receiving TURALIO. Daiichi Sankyo, Inc., and its agents, may contact me or my prescriber by phone, mail or email to manage the TURALIO REMS. Daiichi Sankyo, Inc., and its agents, may use and share my personal health information, including lab tests and prescriptions as part of the TURALIO REMS. My information will be protected and will be used to enroll me into and manage the TURALIO REMS. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TURALIO REMS.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature *</td>
</tr>
<tr>
<td>Name (Printed) *</td>
</tr>
<tr>
<td>Date *</td>
</tr>
<tr>
<td>Jon Snow</td>
</tr>
<tr>
<td>Jon S Snow</td>
</tr>
<tr>
<td>01/09/2032</td>
</tr>
</tbody>
</table>
Patient Enrollment Form Prepopulated

Please visit www.turalorems.com or contact the TURALIO REMS Coordinating Center at 1-833-TURALIO (833-887-2546) to designate up to two additional REMS certified prescribers who can view, edit, and submit REMS paperwork for your TURALIO patients.

Baseline Labs

Assess the patient by obtaining liver tests as stated in the Prescribing Information. If Albumin or PT/INR were not obtained, indicate “not applicable.” Please provide the results below.

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Baseline Value (units, reference range)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST or ALT</td>
<td>23 U/L (normal)</td>
<td>06/15/2021</td>
</tr>
<tr>
<td>ALT or SGPT</td>
<td>12 U/L (normal)</td>
<td>03/11/2021</td>
</tr>
<tr>
<td>GGT</td>
<td>14 U/L (normal)</td>
<td>12/04/2021</td>
</tr>
<tr>
<td>Total Bilirubin</td>
<td>0.8 mg/dL (normal)</td>
<td>04/11/2021</td>
</tr>
<tr>
<td>Direct Bilirubin</td>
<td>0.2 mg/dL (normal)</td>
<td>04/18/2021</td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>27 U/L (normal)</td>
<td>06/15/2021</td>
</tr>
<tr>
<td>Albumin</td>
<td>4.8 g/dL (normal)</td>
<td>01/20/2020</td>
</tr>
<tr>
<td>PT/INR</td>
<td>9.7 s (normal)</td>
<td>12/05/2020</td>
</tr>
</tbody>
</table>

Current Medication

Check box if there are no current medications

Medication

methotrexate - 4 MB, Turalio - 3183103
Submit REMS Bundle

In order to receive TURALIO I must be enrolled in the TURALIO REMS. The TURALIO REMS will collect data to assess the risk of serious liver problems which can be severe and lead to death as described in the Patient Guide. • I agree to enroll in the Patient Registry. • I agree to review the Patient Guide. • I must get blood tests to test my liver as directed by my healthcare provider. • I agree to tell my healthcare provider if I have signs and/or symptoms of liver injury. • My personal information will be shared to enroll me in the Patient Registry so that my health and any liver injury can be evaluated while I am receiving TURALIO. • Daiichi Sankyo, Inc., and its agents, may contact me or my prescriber by phone, mail or email to manage the TURALIO REMS. • Daiichi Sankyo, Inc., and its agents, may use and share my personal health information, including lab tests and prescriptions as part of the TURALIO REMS. My information will be protected and will be used to enroll me into and manage the TURALIO REMS. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TURALIO REMS.

Signature * Name (Printed) * Date *
Jon Snow Jon S Snow 04/21/2022
# Check Status in REMS Admin & Pharmacy

## REMS Admin Status

- **Case Number**: 5d8e702b4f64ce69954af4a5f25cc
- **Status**: Approved

## Pharmacy Status

- **ID**: 6261807673d5e00567f805c
- **Status**: Picked Up
Order Appears in Pharmacy System

Orders Grouped by Status