

Quick Refresher – Pressure Points for Getting Drug Testing Right

Test platform and billing framework; Cost-Effective

Two Broad Categories of Drug Testing

Presumptive

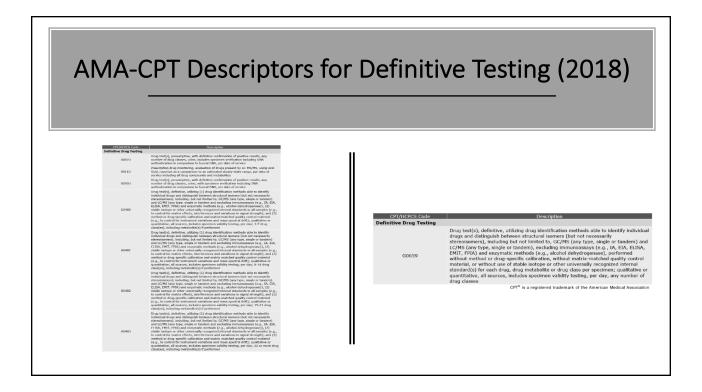
- "Screen"
- Results are generally + or -
- <u>Typically EIA/IA</u> (limited test menu, less specificity/sensitivity) <u>unless</u>
 <u>sophisticated lab</u>, then LC-MS/MS, LDTD, or other non-EIA/IA test method

Definitive

- "Confirm"
- Results are generally quantitative (value)
- Typically LC-MS/MS or similar

AMA-CPT Descriptors for Presumptive Testing (2018)

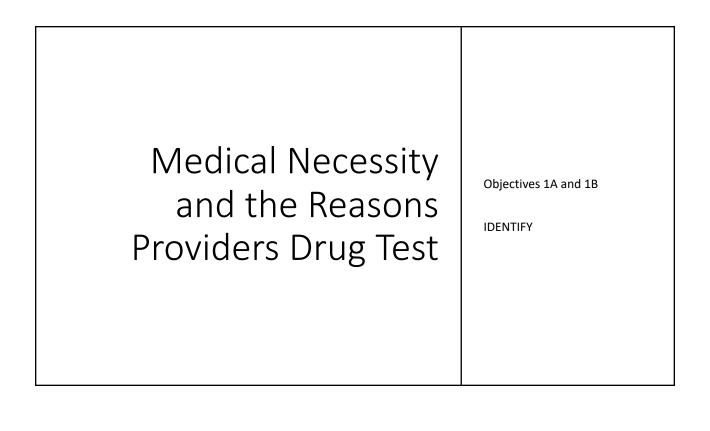
CPT/HCPCS Code	Description
Presumptive Drug Testing	
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

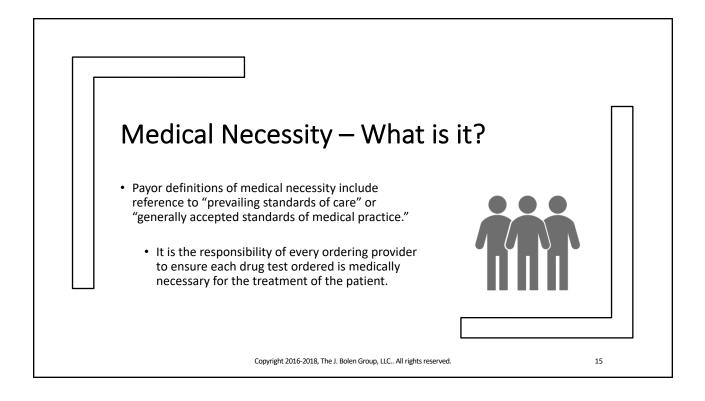


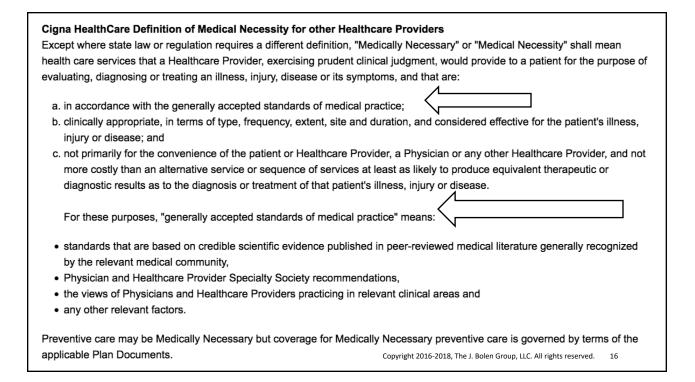
		Test Category	Type of Test	CPT/HCPCS Code	Medicare's CLFS 2018 Reimbursement Fee
		Presumptive	Cassette, Cup, Dipstick	80305 or 80305QW	\$13.46
		Presumptive	Test w/reader	80306	\$17.96
		Presumptive	Chemistry Analyzer (EIA)	80307	\$71.83
2018 Reimbursement for Drug Testing		Presumptive	DESI, DART, LC-MS/MS, LDTD, MALDI, TOF	80307	\$71.83
		Definitive POL	Definitive GC or LC with Mass Spectrometry in the Physician Office Lab	G0659 (# of classes irrelevant)	\$71.83
				G0480 (1 to 7 drug classes)	\$114.43
			GC or LC with Mass Spectrometry or similar NON-EIA/IA test subject to additional lab	G0481 (8 to 14 drug classes)	\$156.59
		Definitive	standard parameters	G0482 (15 to 21 drug classes)	\$198.74
	-			G0483 (22 or more drug classes)	\$246.92

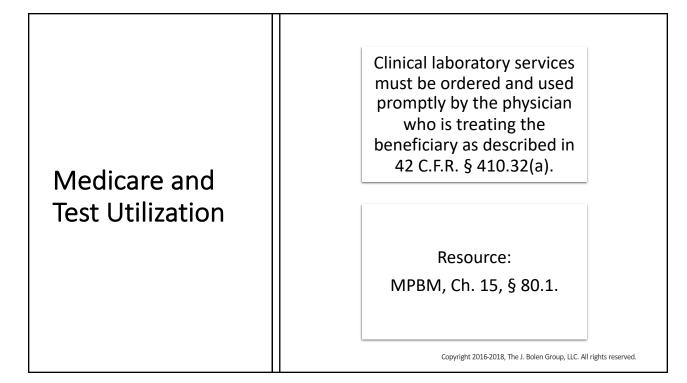
Pain-Related Definitive Drug Class Descriptors (2018)

Class #	Class Descriptor	Class #	Class Descriptor	Class #	Class Descriptor
1	Alcohol	12	Buprenorphine	23	Opioids and Opiate Analogs
2	Alcohol Biomarkers	13	Cannabinoids, Natural	24	Oxycodone
3	Alkaloids	14	Cannabinoids, Synthetic	25	РСР
4	Amphetamines	15	Cocaine	26	Pregabalin
5	Anti-depressants (serotonergic)	16	Ecstasy (MDMA)	27	Propoxyphene
6	Anti-depressants (tricyclic)	17	Fentanyl	28	Sedative Hypnotics
7	Anti-depressants (other)	18	Gabapentin	29	Skeletal Muscle Relaxants
8	Anti-epileptics	19	Heroin	30	Stimulants, Synthetic
9	Anti-psychotics	20	Ketamine	31	Tapentadol
10	Barbiturates	21	Methadone	32	Tramadol
11	Benzodiazepines	22	Opiates	33	Other unspecified







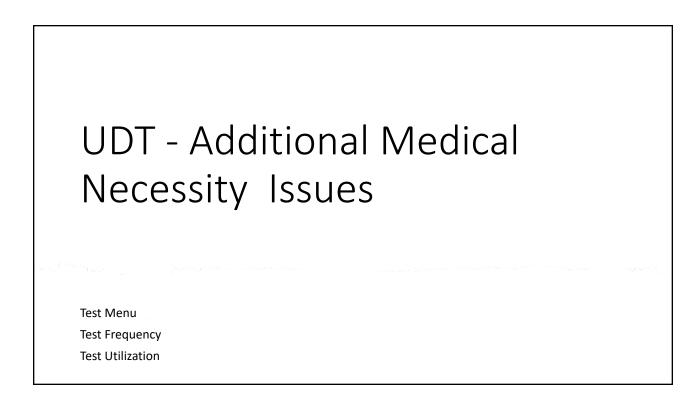


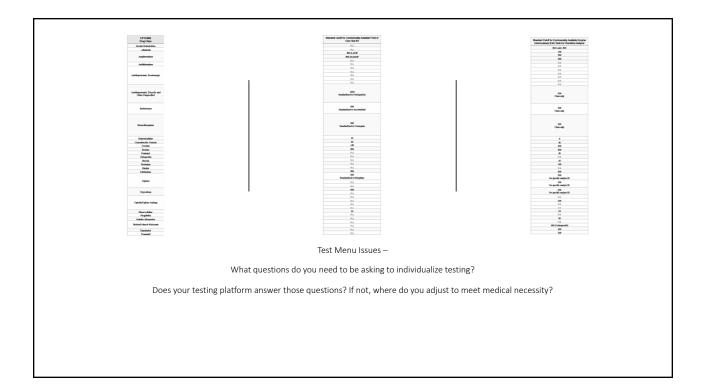
To Prevent Denials
The following conditions must be met:
 Urine drug screenings must be ordered by the physician who is treating the beneficiary, that is, the physician and other eligible professionals who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.
 All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered for the treatment of the individual patient. Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed.
 The physician or other eligible professionals who ordered the test must maintain documentation of medical necessity in the beneficiary's medical record.
 Entities submitting a claim must maintain documentation received from the ordering physician or non- physician practitioner. (See <u>42 Code of Federal Regulations 410.32</u>.)
Medicare and Medical Necessity
(Medicare Learning Network Item - ICN 909412 September 2016)
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STIMULANTS (1)	MUSCLE RELAXANTS (2)	Opiates/Synthetics (3)	Opioids (4)	
Amphetamines, Methylphenidate, Ritlanic Acid, Phentermine	Carisoprodol, Gabapentin, Ketamine, Norketamine, Meprobamate, Pregabalin, Zolpidem	Codeine, Morphine, Hydrocodone, Norhydrocodone, Hydromorphone, Oxycodone, Noroxycodone, Oxymorphone, Buprenorphine, Meperidine	Norbuprenorphine, Fentanyl, Nor Fentanyl, Methadone, EDDP, Tapentadol, Tramadol, O-desmethyltramadol, Propoxyphene	
AMPHETAMINES (5)	BARBITURATES (6)	ILLICITS/OTHERS (7)	TOBACCO (8)	
Methamphetamine	Butalbital, Phenobarbital, Pentobarbital, Amobarbital, Secobarbital	6-MAM, Benzoylecognine, MDA, MDMA, PCP, THC-COOH	Cotinine	
Benzodiazepines (9)		TRICYCLIC ANTIDEPRESSANTS (10) Amitriptyline, Nortriptyline		
7-aminoclonazepam, Alprazc Diazepam, Nordiazepam, Ox a-OH-Midazolam	olam, a-OH-Alprazolam, azepam, Temazepam, Lorazepam,			

Alkaloids (1)	Amphetamines (2)	Antidepressants (TCA) (3)	Barbiturates (4)	Benzodiazepines (5)
Buprenorphine (6)	Cannabinoids, Natural (7)	Cocaine (8)	Ecstasy (9)	Fentanyls (10)
Gabapentin (11)	Heroin (12)	Ketamine (13)	Methylphenidate (14)	Opiates (15)
Oxycodone (16)	Opioids and Opiate Analogs (17)	PCP (18)	Pregabalin (19)	Skeletal Muscle Relaxants (20)
Methadone (21) EDDP	Sedative Hypnotics (22) Zolpidem	Tapentadol (23)	Tramadol (24) O- desmethyltramadol	

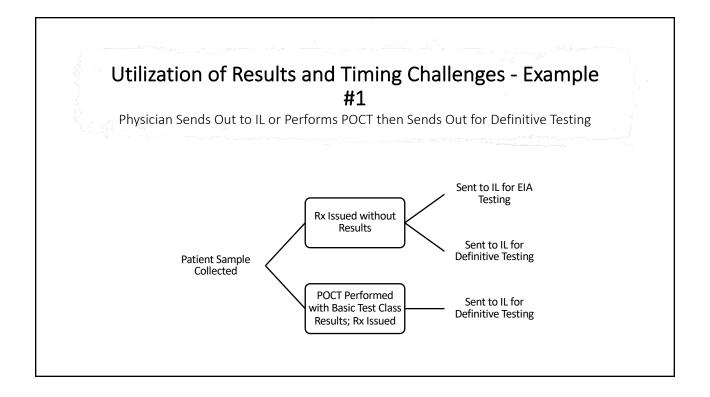
Presumptive Method	Definitive Method	Cost Category	Challenges
EIA by Independent Lab	LC-MS/MS by Independent Lab	Expensive, depending on scope of "reflex and add testing" rules	Getting sufficient information prior to Rx
			Getting timely LC-MS/MS results
POCT Cup or Cassette	LC-MS/MS	Expensive, depending on how Definitive Testing Ordered	Using Results in Timely Fashion
		Skipped billing cup to bill for analyzer, but used cup prior to issuing Rx – Payor may see as fraud/abuse	
OCT Cup and EIA Analyzer by POL	LC-MS/MS by Independent Lab	Expensive	
			Results may not be timely for all or part of patient population
			POL may repeat testing (1) to capture income regardless of
OCT Cup and EIA Analyzer by POL	LC-MS/MS by POL	Expensive	patient drug use history, and (2) because of "lab in a box" scienc challenges.
POCT Cup	None	Inexpensive	Insufficient Information
EIA Analyzer	None	Relatively Inexpensive	Insufficient Information
LC-MS/MS or LDTD "Screen"	None or Tier 1	Cost-effective	Sufficient Information if Test Menus Properly Established
None	LC-MS/MS	Can be expensive depending on how priced, but may also be cost effective when bundled	Turn around time may be an issue, depending on lab Payors may not accept Definitive test code without Presumptiv test and outcomes
		Can be expensive depending on how priced, but may also	Turn around time may be an issue, depending on la Payors may not accept Definitive test code without Presu
ost of T	esting: F	Realities	

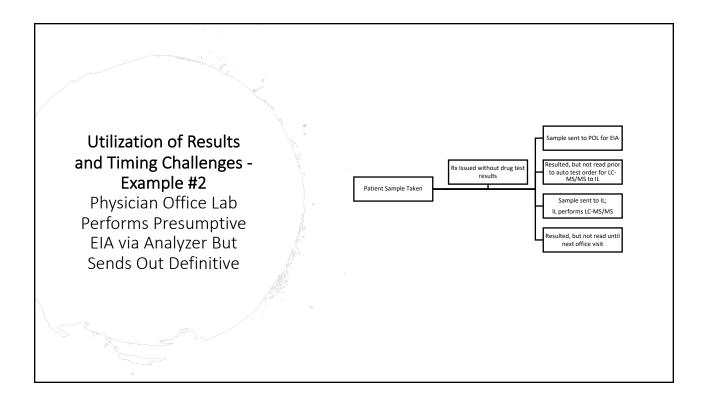


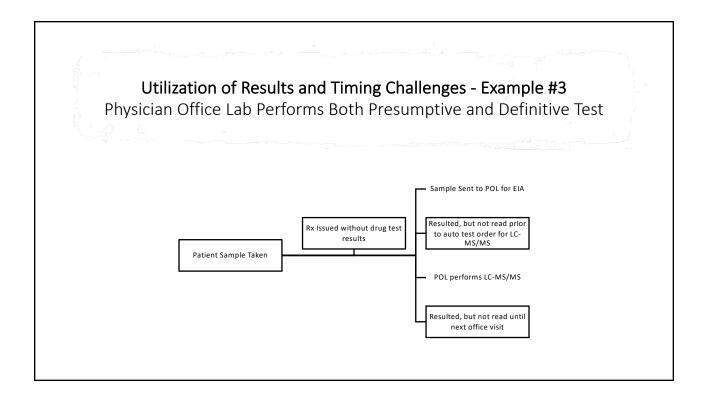


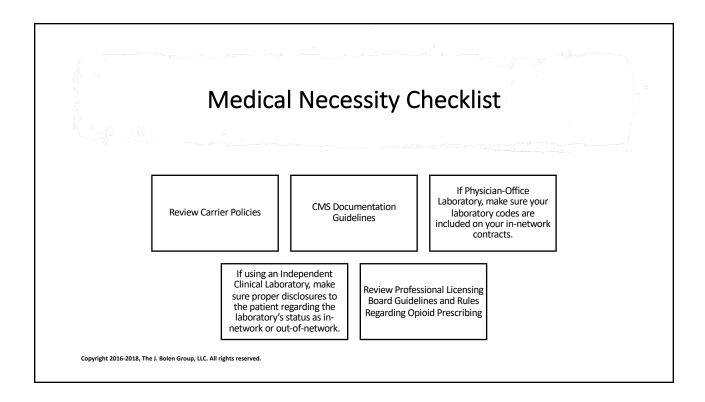
Drug Class* (Only a few drug classes shown for illustration purposes)	POCT	EIA Analyzer	LC-MS or LC-MS/MS
Alcohol	Yes	Yes	See next class
Alcohol metabolites	No	EtG only	EtG and EtS
Amphetamines	Class	Class	Amphetamine, Methamphetamine, D & L Isomer, Phentermine
Barbiturates	Class	Class	Specific analytes (several)
Benzodiazepines	Class	Class	Specific analytes (many)
Buprenorphine	Yes	Yes	Yes, with lower cutoff level
Cocaine	Yes	Yes	Yes, with lower cutoff level
Fentanyl	No	Yes	Yes, with lower cutoff level and parent and metabolite for fentanyl, and other fentanyls, including Carfentanil
Gabapentin, Pregabalin	No	No	Yes
Heroin	No	Yes	Yes, with lower cutoff level and ability to measure codeine, morphine
2	Class	Class (codeine, morphine)	Yes, with lower cutoff levels and ability to detect and measure codeine, morphine, their metabolites
Opiates	Class	Hydrocodone	Yes, with lower cutoff levels and ability to distinguish hydrocodone and its metabolites, from hydromorphone and its metabolites.
Oxycodone	Class	Class	Yes, with lower cutoff level and ability to distinguish oxycodone and its metabolites from oxymorphone and its metabolites.
Opioids and Opiate Analogs	No	Some	Dextromethorphan, Dextrorphan, Meperidine, Normeperidine, Naloxone, Naltrexone, Levorphanol
Tramadol	No	Yes	Yes, with lower cutoff level and ability to specifically identify metabolite

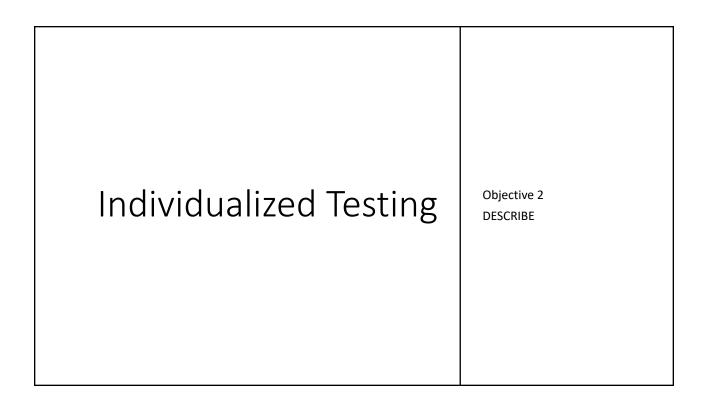
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Payor>	AETNA	ANTHEM BC of CA	CIGNA	HUMANA	UNITED
Effective Date	Summer 2018	6/28/18	2/15/18	7/1/18	7/11/18
	NMT 8/year	NMT 24/year	NMT 32/year and NMT 1 per DOS	NMT 12/year	NMT 18/year and NM per DOS
Presumptive Test Frequency Limitation					
	NMT 8/year	Specific to medical necessity	NMT 16 DOS/Year and NMT 8 classes per DOS	All definitive testing must be justified in writing and by presumptive test results.	NMT 18 annually and 1 per DOS

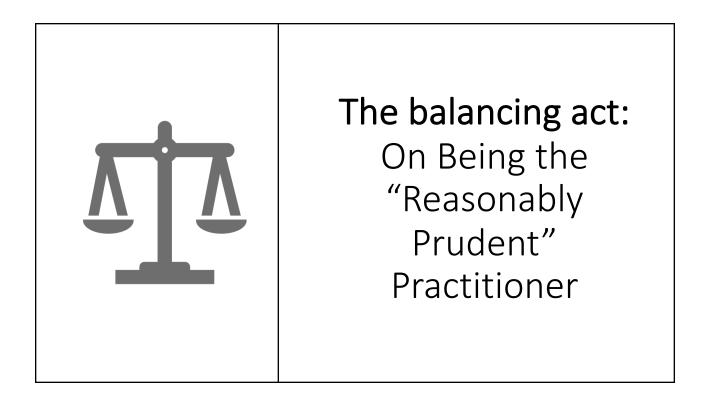


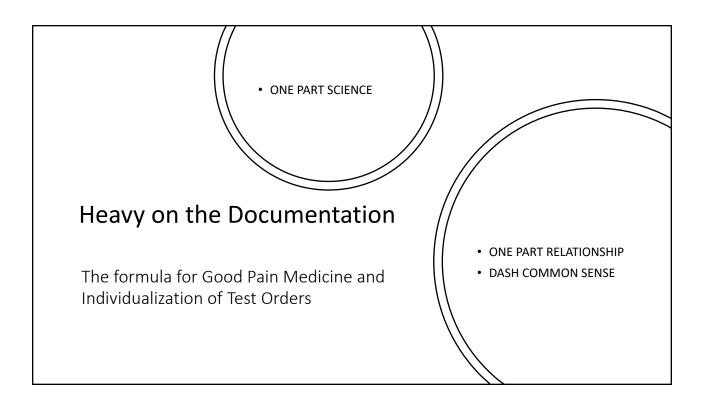


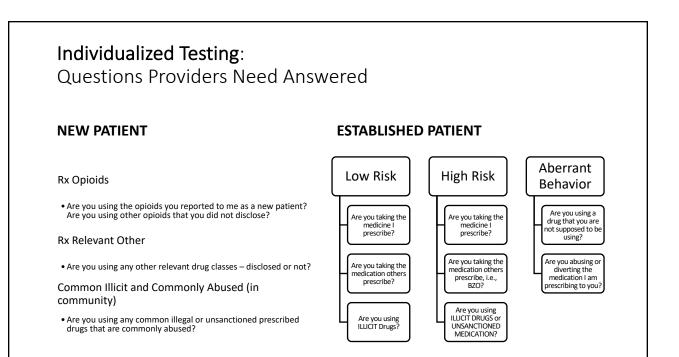


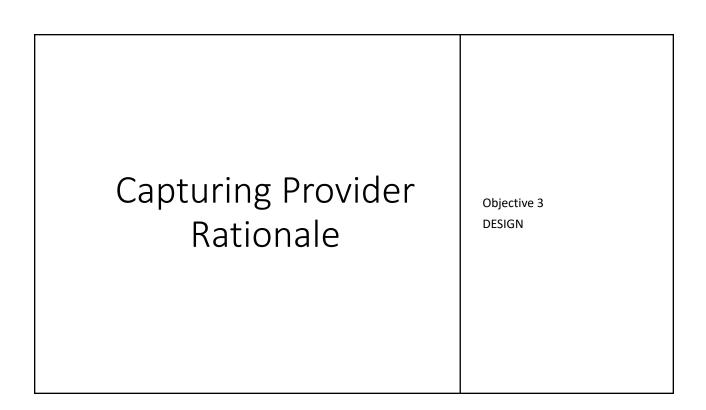


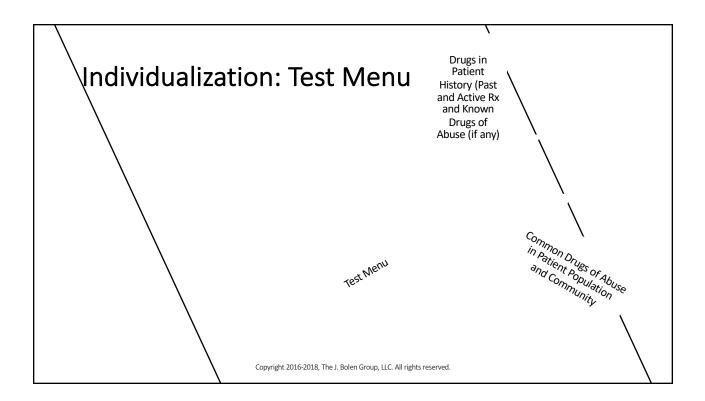










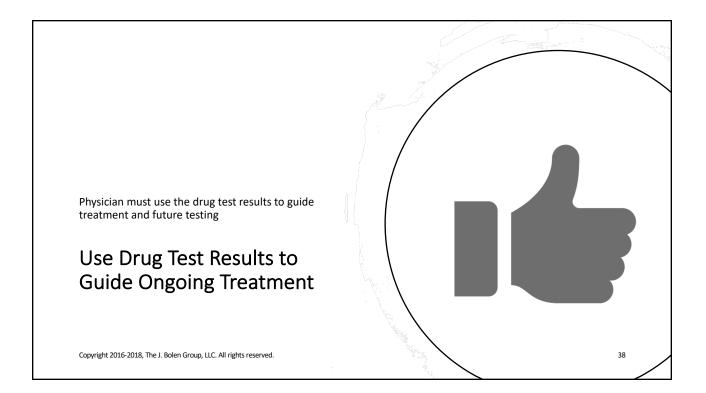


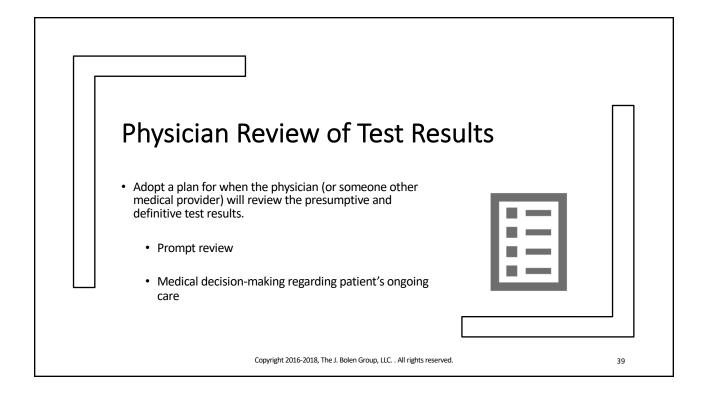
I need to drug test Davy Jones because						
Initial Evaluation and Determining Risk Level	Ongoing Monitoring and Risk Level	Suspected Aberrant, Drug-Related Behavior				
New patient – Is testing before Rx Opioids "Reasonably Prudent"?	Required licensing board monitoring of patient behavior and risk potentials via UDT	Anonymous call reporting patient might be diverting medication				
New patient – Verify Report of Rx Drugs (PDMP) and Test when Treatment Plan Involves Opioids; Control Drug Supply	Periodic evaluation of patient's compliance with Rx treatment plan and elimination of risks associated with use of illicit drugs or unsanctioned prescribed medication	Patient spouse insisting that patient need more medication; wants increased dose despite 9/10 pain report and end of opioid trial period				

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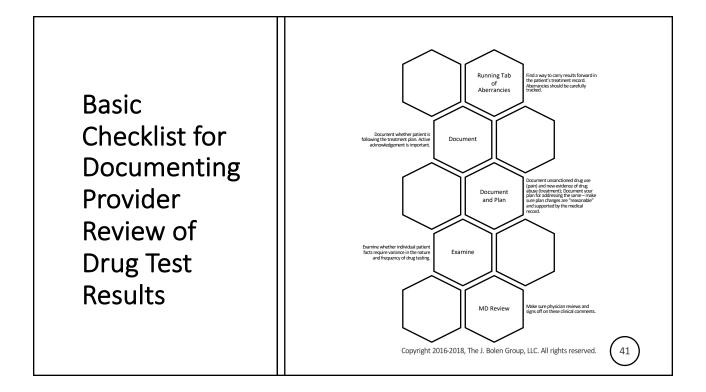
Individualization: What does it look like?
Example in Chronic Pain

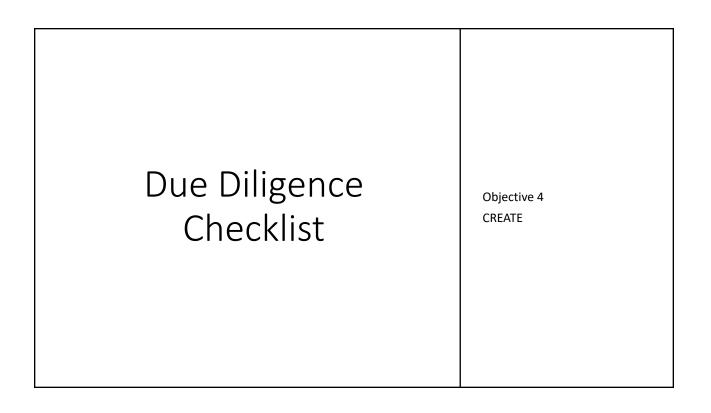
Patient Risk Profile Level	Test Menus (Presumptive/Definitive)	Test Frequency	Test Utilization
New Patient	Full Presumptive, Definitive Testing of Positives and Unexpected Negatives (Rx Medication Match if applicable) Add Practice Profile Drug Classes	1x full then stratify into risk profiles by next visit	Use results (at least presumptive test results) BEFORE prescribing controlled medication or CONTROL Drug Supply
Low Risk	Low Risk Test Profile (Rx Medication Match) Definitive Testing of Positives and Unexpected Negatives Generally, Definitive Drug Class Tier 1	At least 1x every 6 months	Use results to determine when another patient encounter and treatment plan adjustment is necessary. Unless all testing performed by outside lab, presumptive results should be used prior to ordering definitive testing. Definitive results should be used within 24 to 48 hour of report receipt.
Moderate/ High Risk	Mod/High Risk Test Profile (Rx Medication Match) Definitive Testing of Positives and Unexpected Negatives Add Additional Definitive Drug Classes based on Patient and Practice Drugs of Abuse Profile)	At least 2x every 6 months (but varies significantly in applicable literature and state approaches)	Use results to determine when another patient encounter and treatment plan adjustment is necessary. Unless all testing performed by outside lab, presumptive results should be used prior to ordering definitive testing.





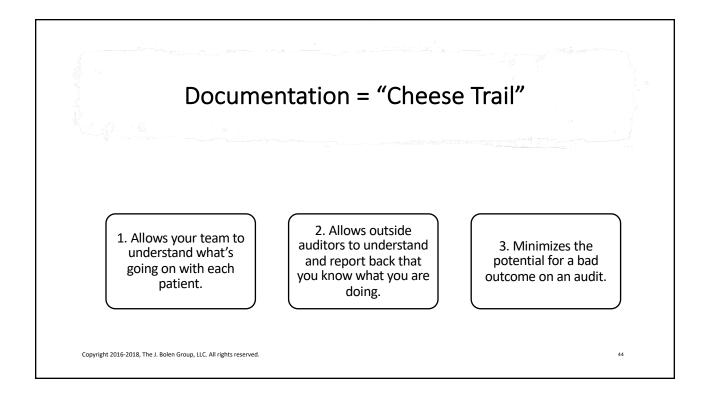
	Prior to Rx	After Office Visit	within 3 days of Test Results	within 5 days of Test Results	Prior to Next Rx	Day of Next Office Visit
Review of POCT (CLIA Waived Results)	0	0	O	O	0	0
Review of Presumptive POL Chemistry Analyzer Results	0	0	0	0	0	0
Review of LC-MS/MS Definitive Results from POL	0	0	0	0	0	0
Review of LC-MS/MS Definitive Results from Independent Laboratory	0	0	0	0	0	0

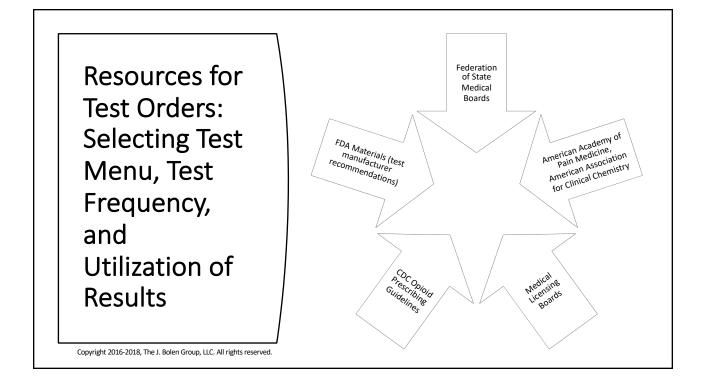




Due Diligence Checklist – Basic Ideas

Task	Comments
Update POCT/POL test menus and add drugs that are most abused, i.e., fentanyl, hydrocodone, heroin	If you have a contract that limits your reagents to those selected by your lab management company, renegotiate it – you are missing critical drugs and possibly wasting money.
Update your test result review timing	If you do not look at analyzer results prior to ordering LC-MS/MS, this weakens your ability to respond to aberrant results and order medically necessary definitive testing. This comment does not apply if you send all specimens to an outside lab for drug testing – presumptive and definitive – because reflex allowed in that situation.
Positivity Rates	Ask your laboratory (POL or Independent) to supply you with a summary of your positivity rates for presumptive and definitive testing on all drugs/drug classes tested. Determine whether positivity rates support your test orders. Consider elimination of 0% positive drugs over large number of patients and time, i.e., propoxyphene and some of the synthetics (practice and regions may vary).
Test Frequency	Evaluate your drug test frequency in light of your state licensing board requirement for drug testing (if any) and Reading Material in this Slide Deck





Resource Position on UDT		Year of Guidance/Policy	
FSMB Guideline for Chronic Use of Opioid Analgesics	Periodic and Unannounced (including Chromatography). Clinical judgement trumps recommendations of frequency. Strong recommendation that if patient is in addiction treatment, test as frequently as necessary to ensure treatment adherence. http://www.fsmb.org/globalassets/advocacy/policies/opioid guidelines as adopted apr il-2017 final.pdf.	2017	
American Academy of Pain Medicine	Contains more specific guidance on test menu, test frequency, and test method. http://www.painmed.org/library/clinical-guidelines/.	2017	
American Association for Clinical Chemistry	Contains more specific guidance on test menu, test frequency, and test method. https://www.aacc.org/media/press-release-archive/2018/01-jan/aacc-releases-practice- guidelines-for-using-laboratory-tests-to-combat-opioid-overdoses.	2018	
American Society of Addiction Medicine	Recent paper on drug testing in the treatment of substance use disorders. https://www.asam.org/resources/guidelines-and-consensus-documents/drug-testing. Copyright 2016-2018, The J. Bolen Gre	2017 up, LLC. All rights reserved.	

Reading File: Urine Drug Testing in Clinical Practice (Doug L. Gourlay, MD, Howard A. Heit, MD, and Caplan, Yale H. Caplan, PhD)

