



Department of Health

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Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

January 22, 2020

DHDTC DAL 20-04
RE: Appropriate Setting for Cardiac
Procedures not Specified in Regulation

Dear Hospital Chief Executive Officer:

The New York State Department of Health (Department) has received a number of inquiries regarding whether it is permissible for PCI capable cardiac catheterization laboratories to perform certain non-surgical cardiac procedures without a licensed cardiac surgery program on the premises of the hospital. In response, the Department consulted with members of the Cardiac Advisory Committee (CAC) to seek their guidance as to the appropriateness of performing these procedures at facilities without cardiac surgery services on site.

After reviewing relevant professional society guidelines and applicable national coverage determinations, the CAC came to conclusions regarding the specific procedures and offered their recommendations to the Department. Following review of these recommendations the Department is now issuing guidance regarding the appropriate setting for these procedures. A list of the specific procedures is attached. This list will be posted on the Department's website at the following link:

https://www.health.ny.gov/professionals/protocols_and_guidelines/

This guidance is being issued under the Department's general regulatory authority at 10 NYCRR Section 405.2(f)(1), which provides that "every patient of the hospital, whether an inpatient, emergency service patient, or outpatient, shall be provided care that meets generally acceptable standards of professional practice". In addition, 10 NYCRR Section 405.29(e)(1) states "Cardiac Catheterization Laboratory Center services must be provided in a manner which protects the health and safety of the patients in accordance with generally accepted standards of medical practice."

It is the expectation of the Department that cardiac surgery centers incorporate this guidance in the annual review of their affiliated PCI capable cardiac catheterization laboratories required by 10 NYCRR 405.29(c)(8)(i), to ensure that procedures performed are in keeping with generally accepted standards of medical practice. Facilities that fail to follow this guidance can be cited.

Should you have any questions, please contact either the Division of Hospitals and Diagnostic and Treatment Centers at (518) 402-1004 or the Cardiac Services Program at (518) 402-1016.

Sincerely,

Deirdre Astin
Director
Division of Hospitals and Diagnostic &
Treatment Centers

Kimberly S. Cozzens, MA
Program Director
Cardiac Services Program

APPROPRIATE SETTING FOR CARDIAC PROCEDURES NOT SPECIFIED IN REGULATION

In consultation with the Cardiac Advisory Committee, the Department is issuing guidance regarding the appropriate setting for the following cardiac procedures:

- Endomyocardial biopsy: This procedure should only be performed at facilities with cardiac surgery onsite.
- Percutaneous Left Ventricular Assist Device, LV to aorta, (i.e. Impella Support devices): Impella devices can be inserted in a Catheterization Laboratory Center without cardiac surgery onsite for patients with hemodynamic instability as part of a strategy of emergency stabilization and transfer to a center with cardiac surgery onsite. Facilities without cardiac surgery onsite should NOT electively admit patients for high risk PCI with Impella support. Impella should only be used when appropriately trained, experienced and credentialed staff are available.
- Transcatheter Aortic Valve Replacement: This procedure should only be performed at facilities with cardiac surgery onsite.
- Transcatheter Mitral Valve Repair (TMVR), e.g. MitraClip: This device should only be used at facilities with cardiac surgery onsite.
- Aortic Valvuloplasty: This procedure should only be performed at facilities with cardiac surgery onsite.
- PFO/ASD Closure devices: Until evidence can be supplied to support the safety of these devices as part of a comprehensive stroke program, this procedure should only be performed at facilities with cardiac surgery onsite.